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SYMBIOSIS INTERNATIONAL (DEEMED UNIVERSITY)

(Established under section 3 of the UGC Act 1956)

Re-Accredited by NAAC with 'A' grade (3.58/4) I Awarded Category - I by UGC

Founder : Prof. Dr. S. B. Mujumdar M.Sc. Ph.D. (Awarded Padma Bhushan and Padma Shri by President of India)

Notification No.SIU/ U-28/ 1056 dated 27th October, 2021

Sub: Standard Operating Procedures (SOPs) for Institutional Ethics Committee (IEC) of Symbiosis International (Deemed University) for Clinical Trials (CT), Bioavailability (BA) and Bioequivalence (BE) Studies

WHEREAS, the New Drugs and Clinical Trial Rules, 2019 was notified by Drugs Controller General of India (DCGI), Ministry of Health and Family Welfare, Government of India.

AND WHEREAS, to formulate the Standard Operating Procedures (SOPs) in line with the New Drugs and Clinical Trial Rules, 2019, the University established an Expert Committee under the Chairmanship of Dean, Faculty of Health Sciences consisting of renowned experts. The committee submitted the SOPs for Institutional Ethics Committee for Clinical Trials (CT), Bioavailability (BA) and Bioequivalence (BE) Studies.

NOW THEREFORE, the Standard Operating Procedures (SOPs) approved by the Board of Management in its meeting held on 11th September, 2021 are hereby notified for information of all concerned. These SOPs are attached as Appendix 'A'.

These Standard Operating Procedures (SOPs) shall come in force from the date of its notification.

Authority : BoM Resolution No. A19 dated 11th September, 2021.

SIU/ U-28/ 21/4331
Date: 27th October, 2021

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Dr. M.S. Shejul
Registrar

Copy for information to: The Hon'ble Chancellor, Pro Chancellor, Vice Chancellor, Principal Director, Symbiosis, Dean-Academics and Administration, Symbiosis, Deans of Faculties of Symbiosis International (Deemed University), Director, Deputy Director, Administrative Officer/ Assistant Administrative Officer/ Officer Superintendent of Constituent Institutes / Departments of SIU, Officers of Symbiosis Society and Symbiosis International (Deemed University).

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Appendix 'A'

Standard Operating Procedures (SOPs) of Institutional Ethics Committee of Symbiosis International (Deemed University)

For

Clinical Trials (CT), Bioavailability (BA) and Bioequivalence (BE) Studies

2021

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COMPOSITION

IEC for Clinical Trials, Bioavailability (BA) and Bioequivalence (BE) Studies

1) **Chairperson:**

2) **Basic Medical Scientist (two)**: Members
   a)
   b)

3) **Scientific Member (two):** Members
   a)
   b)

4) **Clinicians from various institutes (three):** Members
   a)
   b)
   c)

5) **Legal Expert (one): Member**
   a)

6) **Social Scientist (one) / Representative of NGO (one): Member**
   a)
   b)

7) **Philosopher/ Ethicist Theologian (one): Member**
   a)

8) **Lay person from the community (two): Member**
   a)
   b)

9) **Member Secretary:**

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SOP of SOP

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SECTION 1 - PURPOSE OF SOP

This procedure describes the standard format and method for establishing standard operating procedures at Clinical Research Department of Symbiosis International (Deemed University).

SECTION 2 - RESPONSIBILITIES

Include who is responsible for oversight of the adherence to the procedures mentioned in the SOP, performing the activities, or other operational responsibilities.

SECTION 3 - PROCEDURES

1. After identifying need for SOP, Quality Manager decides on the level of detail for the SOP.
2. Quality Manager prepares a step-by-step task list of the activity including who is responsible for each activity.
3. Each activity is evaluated for efficiency, effectiveness, and compliance with the regulations specific to the country, DCGI regulations and other applicable regulations, guidelines and institutional policy.
4. Tools are designed and (attached where applicable) to be used with the SOP such as forms, templates, logs, checklists, annexures etc.
5. The first draft of SOP is completed. Each SOP is reviewed for accuracy and feasibility by the Research Director.
6. All comments and revisions are evaluated and are included in the final version as appropriate.
7. The final version (*including version dates*) is completed and implemented to clinical research staff.

SECTION 4 - IMPLEMENTATION

1. After the SOP is finalized, it is distributed to all clinical research staff.
2. As each SOP is implemented, a training session is conducted to ensure that all study staff understands the requirements of the SOPs and each person can complete their responsibilities as designated in the SOPs. Documentation of the training session is maintained in the training record.
3. Principal Investigator supports the SOPs and the required tasks are to be performed at this site.

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SECTION 5 - THE ADVANTAGES OF HAVING A SOP

1. They provide personnel with numbered step by step instructions on a specific procedure (or procedure used to carry out a method) with minimum variability; SOPs institutionalize individual experience. Despite change in personnel, operations do not change since they are conducted as the written SOPs:

    a. Ensure that the procedures are performed consistently and in compliance with government regulations;
    b. Protect the health and safety of personnel by enabling jobs to be carried out in the safest possible way. They ensure that all of the safety, health, environmental and operational information is available to perform specific procedures with minimal impact;
    c. Facilitate training in procedures, for both new personnel and for those that need re-training (i.e., after extended absence from a position. Having step by step instructions aids trainers to ensure that nothing is missed;
    d. Serve as a historical record for use when modifications are made to that procedure and when the SOP is revised.
    e. Promote quality though consistent collection of the data, even if there are changes in the people undertaking the monitoring; and
    f. Encourage improvements and work evaluation by ensuring that the procedures are completed, and can be used in incident investigations to improve operations and safety practices.

SECTION 6 - SOP REVISIONS

1. Each SOP is reviewed annually. Revisions are made accordingly to account for changes in regulation, site procedure or institutional policy.
2. Revisions are labelled as such with an effective date and a new version date.
3. All previous versions of the SOP are kept in file.
4.

Function	Name	Designation	Signature
Prepared by	**Dr. Manjiri Joshi**	**Head, Clinical Research Dept, SUHRC & SMCW**	
Reviewed by	**Dr. Ravindra Ghooi** **Dr T. Vijaya Sagar**	**Member, IEC** **Dean, SMCW**	
Approved by	**Dr. Raman Gangakhedkar**	**Chairman**	

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Constitution of IEC

The Independent Ethics Committee was first constituted in the year 2014 by the Hon'ble Vice Chancellor of Symbiosis International (Deemed University). It was duly registered with the Drugs Controller General of India (DCGI). It was re-registered on 6th April 2018. Till to date, 3 versions of the SOPs of the IEC have been implemented, the current one is the 4th version. It is now proposed to rename it as the Institutional Ethics Committee, since the Ethics Committees are now reviewing studies from the affiliated organizations Viz. Symbiosis University Hospital and Research Centre (SUHRC), and the Symbiosis Medical College for Women.

SIU is established and managed by Symbiosis Society. Symbiosis Society is a 'Not for Profit' organization established as a Public Charitable Trust on 26th January 1971 by Dr. S. B. Mujumdar and is registered under the Bombay Public Trusts Act 1950 (Reg. No. F/48, Pune) on 26-02-1971 and as a Society registered under the Societies Registration Act 1860 (Reg.No.MAH-679-PN), having its registered office at Senapati Bapat Road, Pune 411 004, in the State of Maharashtra, India.

Till October 2020, the IEC was reviewing proposals concerning Biomedical and Health Research only. No clinical trials were undertaken. However, since then, with the establishment of the Symbiosis University Hospital and Research Centre (SUHRC), and the Symbiosis Medical College for Women, in our re-application to the DCGI, we have specifically mentioned our intention to undertake Clinical Trials (CT). Hence, the current nomenclature of this Ethics Committee would be IEC of SIU (CT). The current SOPs are based on New Drugs and Clinical Trial Rules, 2019, published by Central Drugs Standards Control Organization, Ministry of Health and Family Welfare, on March 19, 2019.

1. Purpose

The IEC of SIU (CT) was established to formalize and specify the institution's commitment to the promotion of high ethical standards in patient care, professional education, clinical research, basic research, and community research.

The purpose of this SOP is to describe the terms of reference (TOR), which provide the framework for constitution, selection, roles, and responsibilities of the IEC of SIU (CT) and procedures for maintaining confidentiality of all activities and documents.

2. Scope

This SOP applies to the constitution of the IEC of SIU (CT), selection, roles and responsibilities of members of the IEC of SIU (CT), and maintenance of confidentiality of all activities and documents.

3. Responsibility

It is the responsibility of the institution to provide the necessary support, facilities and independence to the IEC of SIU (CT) while performing its functions and taking decisions as per the MOU (available with the secretariat) signed between Head of Institute (HOI) (Registrar SIU) and the Chairperson, IEC of SIU (CT).

It is the responsibility of all the IEC of SIU (CT) members and the secretariat to read, understand, and follow this SOP.

3.1 IEC of SIU (CT) responsibilities and objectives:

3.1.1 To ensure competent review and evaluation of all ethical aspects of research projects received.

3.1.2 To ensure compliance with the applicable laws, socio-cultural norms and safeguard welfare of the participating subjects.

3.1.3 To review sponsored studies (Clinical Trials and Bioavailability and Bioequivalence studies).

3.1.4 To educate investigational, administrative, and support staff on ethical issues related to research.

3.1.5 To create, develop, revise, and implement ethical guidelines (SOPs) for research at Symbiosis.

3.1.6 Organize education and training programs to ensure that IEC of SIU (CT) members are qualified to perform their specific duties.

4. Mandate

The IEC of SIU (CT) functions independently to maintain consistent ethical framework in research, and in the integration of ethical values into research activities and policy.

4.1 The purpose of IEC of SIU (CT) is to cultivate a pluralistic and democratic exchange of ethical values, address concerns, and to critically analyze them, looking for opportunities to enhance the ethical integrity of research in the institution.

4.2 The mandate essentially targets ethical aspects of research.

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5. IEC of SIU (CT) terms of reference

The terms of reference of the IEC of SIU (CT) are as follows:

5.1 To improve the standard of research ethics practiced in SIU and to issue guidelines on dilemmas related to research ethics at SIU.

5.2 To ensure that all proposed research projects conform to standard ethical guidelines.

5.3 To provide continuous education in bioethics and ethical aspects of interventional and biomedical research by holding seminars, workshops and interactive discussions for all categories of staff members.

5.4 To function as a forum for redressal of complaints on ethical issues, received from study participants and their families.

6. Ethical basis

6.1 The committee consists of members who collectively have the qualifications and experience to review and evaluate the scientific, medical, and ethical aspects of a proposed research project.

6.2 The IEC of SIU (CT) recognizes that the protocols it approves may also be approved by national and/ or local ethics committees prior to their implementation in specific localities.

6.3 In evaluating protocols and ethical issues, the IEC of SIU (CT) is aware of the diversity of laws, cultures, and practices governing research and medical practices in various countries around the world.

6.4 The IEC of SIU (CT) also seeks to be informed, as appropriate, by national / other local ethics committees and researchers of the impact of the research it has approved.

6.5 The IEC of SIU (CT) is guided in its reflection, advice, and decision by the ethical principles expressed in ICMR Ethical Guidelines 2017 and the Declaration of Helsinki (Revised by 64th WMA general Assembly, Brazil, October 2013)

6.6 It makes further reference to the International Ethical Guidelines for e.g. The Nuremburg Code (1945), the Council of International Organizations of Medical Sciences, the Belmont Report 1979, the International Ethical Guidelines for Biomedical Research Involving Human Subjects (Geneva 2002), and the European Convention on Human Rights and Biomedicine 1977.

6.7 The IEC of SIU (CT) establishes its own Standard Operating Procedures based on the ICMR guidelines (2017), ICH-GCP (E6R2), 2016, Medical Device Rules 2017 and New Drugs and Clinical Trials Rules, 2019, and other applicable guidelines/regulations.

6.8 Increasing scientific and quality of care, rigor and research atmosphere inculcated in this institution staff has led to a significant increase in clinical trials. For various reasons, clinical trials are also coming under close public scrutiny. Hence, there is a strong need for impeccable and efficient management of clinical trials to ensure human rights protection especially of the vulnerable groups. Speed, time, and maintenance of high ethical standards for IEC of SIU (CT) review process are critical expectations for multinational clinical research.

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7. Composition

7.1 The IEC of SIU (CT) will be multidisciplinary and multi-sectoral in composition.

7.2 The committee will consist of a minimum of 7, and a maximum of 15 members as per the current CDSCO guidelines.

7.3 The members will be selected so as to have an equitable representation of specialties in the institution. It includes scientific and non-scientific members, clinician(s) and non – clinician(s), clinical pharmacologist, member(s) of the community, a legal expert or retired judge, expert in ethics / a social scientist, and a layperson to represent different point of views.

7.4 The IEC of SIU (CT) may invite member(s) of specific patient groups or other special interest groups to its meeting if required, based on the requirement of the research area e.g. HIV, genetic disorders, etc. for eliciting their views. Such individuals will have to sign confidentiality agreement (annexure 1) and declare in writing, conflict of interest, if any, prior to attending the meeting. They will attend the meeting in the capacity of an 'observer' and will not have the right to vote.

7.5 The committee will comprise of a Chairperson, a Member Secretary, and 7 – 15 active members (including the Chairperson and member Secretary) who represent an appropriate balance of professional, ethical, legal, cultural, educational, and community interests.

7.6 The committee should have adequate representation of age, gender, community, etc. to safeguard the interests and welfare of all sections of the community / society. Members are expected to be aware of local, social, and cultural norms.

7.7 The members should have varied backgrounds to promote complete and adequate review of research activities commonly conducted.

7.8 The committee will consist of at least 50% of its members who are not affiliated to the institute.

7.1 Composition of IEC of SIU (CT)

The composition should be as follows:

7.1.1 Chairperson (not – affiliated to institute)

7.1.2 Member Secretary (institute staff member)

7.1.3 One or two clinicians (affiliated / not affiliated to institute)

7.1.4 Basic medical scientist(s) / clinical pharmacologist (preferably)

7.1.5 One legal expert, or retired judge, or medico-legal expert

7.1.6 One social scientist / representative of non-governmental voluntary agency / philosopher / ethicist / theologian

7.1.7 One or more lay person from the community

7.1.8 One-woman member

7.1.9 Alternative members: There may be 4 to 5 alternative members of various disciplines appointed. They will be invited to attend the meetings when required.

7.2 Membership

All members will be appointed by the Hon. VC, SIU based on recommendations by Chairperson, IEC of SIU (CT) / Member Secretary.

Criteria for selection of members:

7.2.1 Chairperson:

The Chairperson will be from outside the institution. He / She will be a person with high standing in the society / profession and will have at the minimum more than 5 years of experience of serving on an ethics committee.

7.2.2 Member Secretary:

He / She will be a staff member of the institute. They should have knowledge in clinical research and ethics, personal interest and capacity and good communication skills.

7.2.3 Members:

Members are selected based on their personal capacities, qualification, interests, ethical and/or scientific knowledge and expertise, experience in domain field as well as on their commitment and willingness to volunteer the necessary time and effort for the committee.

Medical scientists and clinicians should have post graduate qualifications. Conflict of interest will be avoided when making appointments, but where unavoidable the same will be declared and there will be transparency with regard to such interests. New members will be identified according to the requirement i.e., as per the composition specified in Section 7.1 of this SOP and provided the potential member fulfils the conditions of the appointment (Ref:7.3.3 in this SOP).

The following attributes are sought for in members of the IEC of SIU (CT):

- Integrity, ethics and professionalism
- Interest and motivation
- Time and effort
- Commitment and availability
- Knowledge, experience and education
- Respect for divergent opinions

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7.3 Terms of Appointment

7.3.1 Duration

- The members of the IEC of SIU (CT) will be appointed for the duration of 3 years.
- The appointment procedure for membership will be followed so that it allows for continuity, the development and maintenance of expertise within the IEC of SIU (CT), and the regular input of fresh ideas and approaches.
- The members can be re-appointed and there will be no limit on the number of times the membership is renewed. Renewal of membership will be based on the recommendation of the Chairperson and Member Secretary of IEC of SIU (CT).
- Alternate members will be appointed to fulfil the quorum requirements. An alternate member can be a member of another committee of the institution or an outsider.
- A Member Secretary, Chairperson or member may be newly appointed preferably before the completion of the tenure of the existing appointed committee. The appointment will be effective for the remaining tenure of the existing committee.

7.3.2 Appointment of new member(s)

- The IEC of SIU (CT) members will be appointed by the HOI.
- New members will be appointed under the following circumstances –
  - When a regular member completes his/her tenure
  - If a regular member resigns before the tenure is completed
  - If a regular member ceases to be a member for any reason including death or disqualification
  - At HOI's discretion, provided the member fulfills the condition of appointment.
- New members will be identified by the member Secretary according to the membership requirement (i.e., as per the composition of the committee and provided the member fulfils the conditions of appointment). The name(s) of the new member(s) to be appointed may be suggested by the IEC of SIU (CT) members and the Chairperson to the member Secretary. The member Secretary will inform the HOI. The final decision of appointment will be taken by the HOI.
- Any change in membership or constitution of the EC will be intimated in writing to the DCGI within 30 working days.

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7.3.3 Conditions of appointment

- Members to be appointed on the IEC of SIU (CT) will need to fulfill the following conditions:
  - Name, age, gender, profession, and affiliation of IEC of SIU (CT) members will be publicized.
  - Members must accept the appointment in writing.
  - Submit a recently signed and updated CV.
  - Submit training certificates in ethics and /or GCP (if not available at the time of induction as member of the IEC of SIU (CT), it must be submitted within 6 months of appointment).
  - Read, understand, accept, and follow the Conflict of interest (COI) policy, in case of COI, it must be disclosed.
  - Members must apprise themselves of the relevant documents, codes, GCP, ICH guidelines, the ICMR code, NDCTR Rules 2019, IEC of SIU (CT) SOPs., and other applicable guidelines. Members are required to sign the confidentiality agreement (annexure 1) at the start of their term. The confidentiality agreement protects the privacy and confidentiality of all parties whose information may be disclosed to the IEC of SIU (CT) in the course of its work.
  - An investigator can be a member of the IEC of SIU (CT); however, the investigator member cannot participate in the review and approval process for any project in which he or she is a PI, Co-Investigator or has a potential conflict of interest.

7.4 Reconstitution

7.4.1 The committee will be reconstituted every 3 years.

7.4.2 At least 2 members of the IEC of SIU (CT) will be replaced in the reconstituted IEC of SIU (CT).

7.4.3 The process of renewal will be as follows:

- Selection of Member Secretary and other members should be done well in advance.
- Designated Member Secretary should be inducted in the committee as a member before he/she takes on the mantle in the new IEC of SIU (CT).
- Other member designees may attend the board meeting as 'observers' before starting their tenure as an IEC of SIU (CT) member.

7.4.4 If a member resigns, or ceases to be a member due to disqualification, or death, a new member will be appointed for the remaining term.

7.4.5 The new member will be appointed as per the conditions of appointment stated above (section 7.3.3).

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7.5 Resignation / Replacement procedure

7.5.1 IEC of SIU (CT) member(s) who decide to resign must provide the HOI, and Chairperson the written notification of his/her proposed resignation date at least 30 calendar days prior to the next scheduled meeting.

7.5.2 The member may or may not assign reasons for resignation. The resignation will become effective from the day it is accepted by the HOI.

7.5.3 The members who have resigned may be replaced at the discretion of the appointing authority.

7.5.4 HOI will appoint a new member, falling in the same category of membership e.g., NGO representative with NGO representative. The recommendations may be sought from the resigning member. Appointment of the member to be replaced will be made in consultation with member Secretary and /or Chairperson

7.6 Disqualification / discontinuation procedure

A member may be relieved or disqualified of his/her membership in case of –

7.6.1 Conduct unbecoming of a member of the Ethics Committee

A member may be disqualified from continuance should (EC) determine by a majority in a meeting specifically called for the purpose that the member's conduct has been inappropriate (misconduct under the Code of Medical Ethics).

- The process will be initiated if IEC of SIU (CT) Chairperson or Member Secretary receives a communication in writing (from a member of the committee or of the public or the HOI) alleging misconduct by the member.
- The Chairperson will satisfy himself/herself that a prima facie case exists before initiating action. If, in the opinion of the Chairperson, the matter is of grave significance where integrity of IEC of SIU (CT) will be questioned, the Chairperson may suspend the membership of the concerned IEC of SIU (CT) member till final decision is taken by IEC of SIU (CT). During the period of suspension, the concerned individual will not have rights, privileges or responsibilities of an IEC of SIU (CT) member and will not perform any duties of IEC of SIU (CT) member including attend meetings.
- The Chairperson may call for a meeting of the IEC of SIU (CT) specifically to discuss this issue or the matter will be taken up for discussion at a regular meeting of the committee (whichever is earlier). The meeting convened will follow the usual rules of quorum. The allegation will be discussed at the IEC of SIU (CT) meeting and the member alleged of misconduct will be provided adequate opportunity to defend himself / herself.
- The member would stand disqualified, if members present approve of disqualification by voting (voting by majority of members present in the meeting). The Chairperson will convey the disqualification to the concerned member through written communication.

7.6.2 If a member fails to attend three consecutive meetings without prior intimation to IEC of SIU (CT) or four consecutive meetings (informed or uninformed), the following process will be conducted:

- The member Secretary will inform the Chairperson, in writing, if a member has not attended more than three consecutive regular meetings of the IEC of SIU (CT) without prior intimation.
- The Chairperson will initiate the process of review of membership of such a member by advising the member Secretary to include the matter in the agenda of the next regular IEC of SIU (CT) meeting.
- A written communication will be sent to the concerned IEC of SIU (CT) member informing him/her that the issue of discontinuation would be discussed at the meeting inviting the member to be present at the meeting to put up his/her case. Alternately, the concerned IEC of SIU (CT) member will be allowed to state his/her arguments regarding unauthorized absence in writing via a letter addressed to the Chairperson.
- The matter will be discussed and reviewed at the IEC of SIU (CT) meeting. The concerned member will be provided adequate opportunity to represent his/her case. A written communication, if received from the concerned member will be read and reviewed at the meeting.
- If deemed necessary, the IEC of SIU (CT) may decide to discontinue the membership; the Chairperson will communicate the recommendation to HOI for necessary action.

- The Chairperson or Member Secretary / additional Member Secretary will inform the IEC of SIU (CT) member about the cessation of membership by a confidential written communication and to other members of IEC of SIU (CT) at the next meeting of IEC of SIU (CT).

In all such situations/circumstances, HOI will serve a letter of termination to the member. Documentation of the termination will be recorded in the minutes of the meeting of the next duly constituted IEC of SIU (CT) meeting and the IEC of SIU (CT) membership circular/roster will be revised. Revision of membership will be informed to DCGI.

8. Independent Consultant (IC) / Subject expert

8.1 The IEC of SIU (CT) may call upon, independent consultants who may provide special expertise to the IEC of SIU (CT) on proposed research protocols, when the Chairperson / Member Secretary/ or the IEC of SIU (CT) members determine that a study will involve procedures or information that is not within the area of expertise of the IEC of SIU (CT) members. An IC may be from within the institute or from outside of the institute.

8.2 ICs will be appointed by the HOI based on the suggestions made by the Member Secretary / Chairperson for an IEC of SIU (CT) term.

8.3 Member Secretary will invite IC(s) in writing to assist the review of the research study and provide his/her independent opinion in writing as and when required. This may be done after seeking concurrence confirming availability of the IC through telephonic / electronic communication.

8.4 A list of ICs will be maintained by the secretariat.

8.5 IC(s) may be specialists in ethical or legal aspects, specific diseases or methodologies, (e.g., genetic disorders, stem cell research, pediatrics, etc.) or they may be representative(s) of community (ies), patient(s), or special interest group(s).

8.6 IC(s) will sign the confidentiality agreement *(annexure 1)* and conflict of interest agreement regarding the meeting, deliberations, and related matters.

8.7 The consultant(s) or subject expert(s) will not vote for taking any decision.

9. Hierarchy

9.1 There will be one Chairperson, one-Member Secretary (wherever applicable) appointed from amongst the members.

9.2 The Chairperson will head the committee.

9.3 The Member Secretary will be the guardian of all documents and funds in the possession of the committee.

9.4 Other IEC of SIU (CT) members will be regular committee members with equal ranking.

10. Functions of office bearers

The IEC of SIU (CT) will have the following office bearers who have the expertise and professional qualifications to review the documents received.

10.1 Chairperson

10.1.1 The Chairperson will be responsible for conducting committee meetings, leading all discussions and deliberations pertinent to the review of research proposals.

10.1.2 The Chairperson will preside over all elections as well as administrative and financial matters pertinent to the committee's functions. The Chairperson will represent the IEC of SIU (CT) at various meetings and forums.

10.1.3 The Chairperson will sign documents and communications related to IEC of SIU (CT) functioning (wherever applicable / mandatory).

10.1.4 In case of anticipated absence of Chairperson at a planned meeting, the Chairperson will nominate an external committee member as acting Chairperson or the members present may elect the Chairperson from amongst the external members. The acting Chairperson will have all the powers of the Chairperson for that meeting.

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10.2 Member Secretary will:

10.2.1 Receive research proposals.

10.2.2 Sign documents and communications related to IEC of SIU (CT) functioning (wherever applicable).

10.2.3 Communicate with the IEC of SIU (CT) members and applicants/ investigators.

10.2.4 Notify the Principal Investigator regarding IEC of SIU (CT) decisions related to the submitted research proposal.

10.2.5 Arrange for training of personnel and IEC of SIU (CT) members.

10.2.6 Organize and conduct IEC of SIU (CT) meeting, prepare minutes, and maintain documentation.

10.2.7 Organize the preparations, review, revision and distribution of SOPs and guidelines.

10.2.8 Provide necessary administrative support for IEC of SIU (CT) related activities to the Chairperson.

10.2.9 Provide updates on relevant and contemporary issues related to the ethics in the domain of research as well as relevant contemporary literature to the committee members.

10.2.10 Receive ethics committee review processing fees (for sponsored studies) and issue official receipts for the same (whenever applicable).

10.2.11 Delegate various responsibilities to appropriate and authorized individuals.

10.2.12 Ensure adherence of IEC of SIU (CT) functioning as per SOPs.

10.2.13 Prepare for audits and inspections.

10.2.14 Correspondence with regulatory authorities e.g.: CDSCO.

10.2.15 Prepare and make available for scrutiny by auditors'/ inspector's annual reports/ and annual financial statements of the IEC of SIU (CT).

10.3 IEC of SIU (CT) members

10.3.1 Attend IEC of SIU (CT) meetings and participate in discussions and deliberations so that appropriate decisions can be arrived at.

10.3.2 Review and discuss research proposals submitted for evaluation.

10.3.3 Discuss Serious Adverse Event (SAE) reports and recommend appropriate action(s)

10.3.4 Review the progress reports and monitor ongoing studies as appropriate. To provide approval for study continuation or completion.

10.3.5 Conduct onsite visits whenever needed.

10.3.6 Evaluate final reports and outcomes.

10.3.7 Maintain confidentiality of the documents and deliberations of IEC of SIU (CT) meetings.

10.3.8 Declare conflict of interest, if any, in writing to the Chairperson, at the particular meeting.

10.3.9 Participate in continuing education activities in biomedical ethics and biomedical research.

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10.3.10 Provide information and documents related to training obtained in biomedical ethics and research, stem cell research to the IEC of SIU (CT) secretariat.

10.3.11 Provide an updated CV when requested for by the IEC of SIU (CT) secretariat.

10.3.12 Carry out the task delegated by Chairperson, Member Secretary and additional Member Secretary.

10.3.13 Assist Chairperson, Member Secretary and Additional Member Secretary in carrying out IEC of SIU (CT) work as per SOPs.

10.3.14 Be updated on relevant laws and regulations.

In addition, it is mainly the responsibility of the social scientist and lay person to review, discuss, and deliberate the Participant Information Sheet (PIS), Informed Consent Document (ICD), translations and their back translations and other documents related to subject recruitment. The legal expert is essentially required to review, discuss and deliberate on trial agreement and ICD.

11. Responsibilities:

11.1 Chairperson:

11.1.1 Conduct EC meetings and be accountable for independent and efficient functioning of the committee.

11.1.2 Ensure active participation of all members (particularly non-affiliated, non-medical/ non- technical) in all discussions and deliberations.

11.1.3 Ratify minutes of the previous meetings.

11.1.4 In case of anticipated absence of Chairperson at a planned meeting, the Chairperson should nominate a committee member as Acting Chairperson or the members present may elect an Acting Chairperson on the day of the meeting. The Acting Chairperson should be a non-affiliated person to the institute and will have all the powers of the Chairperson for that meeting.

11.1.5 Seek COI declaration from members and ensure quorum and fair decision making.

11.1.6 Handle complaints against researchers, EC members, conflict of interest issues and requests for use of EC data, etc.

11.2 Member Secretary:

11.2.1 Organize an effective and efficient procedure for receiving, preparing, circulating and maintaining each proposal for review.

11.2.2 Schedule EC meetings, prepare the agenda and minutes.

11.2.3 Organize EC documentation, communication and archiving.

11.2.4 Ensure training of EC secretariat and EC members.

11.2.5 Ensure SOPs are updated periodically and as and when required.

11.2.6 Ensure adherence of EC functioning to the SOPs.

11.2.7 Prepare for and respond to audits and inspections.

11.2.8 Ensure completeness of documentation at the time of receipt and timely inclusion in agenda for EC review.

11.2.9 Assess the need for expedited review/ exemption from review or full review.

11.2.10 Assess the need to obtain prior scientific review, invite independent consultant, patient or community representatives.

11.2.11 Ensure quorum during the meeting and record discussions and decisions.

11.3 Basic medical scientist / Pharmacologist:

11.3.1 Scientific and ethical review with special emphasis on the intervention, benefit-risk analysis, research design, methodology and statistics, continuing review process, SAE, protocol deviation, progress and completion report

11.3.2 For clinical trials, pharmacologist to review the drug safety and pharmacodynamics

11.4 Clinician:

11.4.1 Scientific review of protocols including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study, and statistics

11.4.2 Ongoing review of the protocol (SAE, protocol deviation or violation, progress and completion report)

11.4.3 Review medical care, facility and appropriateness of the principal investigator, provision for medical care, management and compensation.

11.4.4 Thorough review of protocol, investigators brochure (if applicable) and all other protocol details and submitted documents.

11.5 Legal expert:

11.5.1 Ethical review of the proposal, ICD along with translations, MoU / Clinical Trial Agreement (CTA), regulatory approval, insurance document, other site approvals, researcher's undertaking, protocol specific other permissions, such as, stem cell committee for stem cell research, Health Ministry Screening Committee (HMSC) for international collaboration, compliance with guidelines, etc.

11.5.2 Interpret and inform EC members about new regulations if any

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11.6 Social scientist / philosopher / ethicist / theologian:

11.6.1 Ethical review of the proposal, ICD along with the translations.

11.6.2 Assess impact on community involvement, socio–cultural context, religious or philosophical context, if any

11.6.3 Serve as a patient/participant/ societal / community representative and bring in ethical and societal concerns.

11.7 Lay person:

11.7.1 Ethical review of the proposal, ICD along with translation(s).

11.7.2 Evaluate benefits and risks from the participant's perspective and opine whether benefits justify the risks.

11.7.3 Serve as a patient/participant/ community representative and bring in ethical and societal concerns.

11.7.4 Assess on societal aspects if any.

12. Secretariat staff and functions

12.1 Staff

12.1.1 Secretariat is composed of Member Secretary / additional Member Secretary and the administrative supporting staff.

12.1.2 The supporting staff consists of staff members of SIU appointed by the HOI.

12.1.3 The administrative staff will support the Member Secretary / additional Member Secretary in all their functions.

12.1.4 All the staff of the secretariat will sign confidentiality agreement which should be filed and stored in the IEC of SIU (CT) office (annexure 1).

12.2 Functions

The secretariat shall have the following functions:

12.2.1 Organizing an effective and efficient tracking procedure for approval of each proposal received.

12.2.2 Preparation, maintenance and distribution of study files.

12.2.3 Organize IEC of SIU (CT) meetings regularly.

12.2.4 Prepare agenda and minutes of the meetings.

12.2.5 Maintain IEC of SIU (CT) documentation and archive them.

12.2.6 Communicate with IEC of SIU (CT) members and Principal Investigators (PIs).

12.2.7 Arrange training for personnel and IEC of SIU (CT) members.

12.2.8 Provide necessary administrative support for IEC of SIU (CT) related activities to the Member Secretary / additional Member Secretary.

12.2.9 Ensure receipt of processing fees for industry sponsored studies and issue official receipts for the same.

12.2.10 Archive files of completed studies for the required duration.

12.3 The IEC of SIU (CT) administrative staff: Working rules

12.3.1 There will be administrative staff (administrator/officer(s) and attendant(s) /helper(s)) who will help the IEC of SIU (CT) Chairperson and Member Secretary in executing functions of the IEC of SIU (CT). Also, to maintain records and facilitate financial aspects of research studies and other related matters. Additional staff may be appointed and duties assigned, as and when deemed necessary by the IEC of SIU (CT). The eligibility criteria for new staff to be appointed will be laid down depending on the required job profile. The need for appointment of administrative staff, job profile and qualifications may be recommended by IEC of SIU (CT) members during a regular IEC of SIU (CT) meeting and will be recorded in minutes and forwarded to the HOI.

12.3.2 The administrative staff will be appointed by conducting formal interviews (to be conducted by the HR department) liaising with the IEC of SIU (CT) Chairperson, Member Secretary, additional Member Secretary, and secretariat.

12.3.3 Duties of the administrative officer(s) staff

- Correspondence with the IEC of SIU (CT) members and external experts
- Correspondence with the Investigators
- Pre and post IEC of SIU (CT) meeting arrangements
- Preparing agenda and minutes of the IEC of SIU (CT) meetings
- Answering queries of the investigators
- Filing study related documents
- Archiving and maintaining the study files
- Maintaining the project data base sheet
- Arranging training sessions
- Managing the financial accounts and related details

12.3.5 The administrative staff will report to the Chairperson and/or Member Secretary/ Additional Member Secretary.

12.3.6 The office timing for the administrative staff will be as per SIU rules & regulations.

12.3.7 The administrative staff will avail leaves as per SIU norms.

12.3.8 Duties of the attendant(s) /helper(s)

- Assisting the secretariat in arranging the IEC of SIU (CT) meetings
- Dispatching sets of study documents to IEC of SIU (CT) members and external experts
- Receiving the study related documents from and dispatching the IEC of SIU (CT) letters to the investigators
- Filing study related documents
- Archiving and maintaining the study files
- Correspondence with the IEC of SIU (CT) members and external experts

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13. Quorum requirements (as per current CDSCO guidelines)

13.1 A minimum of five (5) members (at least 50% of the EC members) are required to form the requisite quorum without which decision(s) regarding the project(s) should not be taken. The quorum should preferably consist of:

- 13.1.1 Basic medical scientists (preferably a clinical pharmacologist)
- 13.1.2 Clinician(s)
- 13.1.3 Legal expert
- 13.1.4 Social scientist or representation of non-governmental voluntary agency or philosopher or ethicist or theologian or similar person
- 13.1.5 Lay person from the community

The above members in addition to the Chairperson and Member Secretary constitute the quorum for the meeting.

13.2 In any case, the ethics committee must include at least one member whose primary area of interest/ specialization is nonscientific and at least one member who is independent of the institution / trial site. Besides, there should be appropriate gender representation on the IEC of SIU (CT).

- 13.2.1 No quorum should consist entirely of members of one profession or one gender.
- 13.2.2 In the absence of the Chairperson, the members present at the meeting will request one of the external members to act as the Chairperson, if Chairperson has not nominated one.
- 13.2.3 With the permission of the Chairperson a permanent invitee member (statistician /any other expert) can attend the meeting who will not take part in decision making.

14. References:

14.1 New Drugs and Clinical Trial Rule 2019

14.2 Medical Device Rules 2017

14.3 National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, ICMR 2017.

14.4 ICH GCP (E6R) 2016

14.5 The Declaration of Helsinki 2013 Revision

14.6 The Belmont Report 1979

Function	Name	Designation	Signature
Prepared by	**Dr. Manjiri Joshi**	**Head, Clinical Research Dept, SUHRC & SMCW**	
Reviewed by	**Dr. Ravindra Ghooi** **Dr T. Vijaya Sagar**	**Member, IEC** **Dean, SMCW**	
Approved by	**Dr. Raman Gangakhedkar**	**Chairman**	

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IEC for Clinical Trials, Bioavailability (BA) and Bioequivalence (BE) Studies	Title: Conflict of Interest and Confidentiality	SOP No: A2: Conflict of Interest and Confidentiality
	Version: 02	Preparation Date: 18 June 2021
	Effective Date:	Review Date:

Conflict of Interest and Confidentiality

Like Caesar's wife, the IEC should not only be fair, but also be seen to be fair. The just image of the IEC takes a beating if its members have either a Conflict of Interest or violate the privacy and confidentiality of information that they come to know in the discharge of their duties.

1. Purpose

This SOP describes Conflict of Interest (COI) and Privacy and Confidentiality in clinical research. It also provides guidelines for handling the same, attempting to manage the impact of violation thereof.

2. Scope

This SOP applies to all investigators of SIU (whether on staff or students or associates), any non-SIU investigators whose research studies are reviewed and approved by IEC of SIU (CT). It also applies to all regular and alternate members of the IEC and staff as well as experts that may be invited to advise the IEC of SIU (CT).

3. Responsibility

All IEC of SIU (CT) members (regular and alternate) are responsible for understanding the definition COI and for self-identifying and disclosing it. The Chairperson would need to ensure that COI is identified, and declared by all members and managed during initial and continuing review of research studies.

4. Definitions, Type and Mandate

4.1 Definitions

Conflict of interest: It is a set of conditions in which professional judgment concerning a primary interest like patient's welfare or the validity of research tends to be or appears to be unduly influenced by a secondary interest like non-financial (personal, academic or political) or financial gain.

4.2 Types of COI

A personal COI is said to exist when

4.2.1 There is an immediate family relationship (e.g.: spouse, parent or parent of a spouse, child or child of a spouse, sibling or sibling of a spouse, or a dependent -who resides with an IEC of SIU (CT) member or consultant or who receives 50% or more support from an IEC of SIU (CT) member, regardless of age) or other close personal relationship ("step" relationships included) with the investigator, or with co-investigators.

4.2.2 IEC of SIU (CT) member or his/her immediate family member serves as a contributor to the research project as a collaborator, consultant, research staff or financer.

4.2.3 Research study is submitted by a departmental colleague/senior (may be regarded as a personal conflicting interest if applicable)

4.2.4 A professional COI means the IEC of SIU (CT) member or his/her immediate family member serves as trustee, director, manager, or scientific advisor of the funding agency sponsoring the research.

4.2.5 A financial COI for IEC of SIU (CT) members and immediate family exists if the IEC of SIU (CT) member or the spouse or dependent of a member receives monetary benefits including, but not limited to, salary or payments for other services (e.g., consulting fees or honoraria), equity interests (e.g., stock, stock options, or any other ownership interests) and intellectual property rights (e.g., patents, copyrights, product or service being evaluated).

4.3 Mandate

There should be no conflict of interest.

4.3.1 The members shall voluntarily withdraw from the Ethics committee meeting while making a decision on an application which evokes conflict of interest and this may be indicated in writing to the chairman prior to the review of the proposal and will be recorded in the minutes.

4.3.2 All members shall sign a declaration on conflict of interest.

4.3.3 If one of the members has her/his own proposal for review, then the member should not participate when the project is being discussed".

5. Detailed Instructions

5.1 Voluntary disclosure regarding COI by IEC of SIU (CT) member - The IEC of SIU (CT) member should determine whether he/she has a COI before reviewing research and declare all certain or potential conflicts of interest prior to engaging in any review process in writing using the form Conflict of interest / Declaration of IEC of SIU (CT) members (annexure 1) and Financial disclosure form (annexure 2).

5.2 IEC of SIU (CT) members should not participate in discussion, or decision making on research proposals applications reviewed at any level (exempt, expedited, or full-board) when they have conflicts of interest except to provide information requested by the IEC of SIU (CT).

5.3 If an IEC of SIU (CT) member has a COI for review outside a meeting (e.g., the expedited procedure/ amendments), he or she should notify the IEC of SIU (CT) Secretariat and return the documents.

5.4 If an IEC of SIU (CT) member has a COI for a study for which he or she has been assigned as a primary reviewer, he or she will inform the IEC of SIU (CT) secretariat so that the review is re-assigned to other members.

5.5 If an IEC of SIU (CT) member has a COI for review of research study at a meeting, he or she will inform the Chairperson and leave the meeting room while discussion of the study takes place. He/she may stay in the meeting room only to answer questions about the research. This is applicable also for IEC of SIU (CT) meetings in which serious adverse events, deviations/violations, amendments/ continuing review reports related to studies are discussed.

5.6 Recusal - IEC of SIU (CT) member who declares COI and leaves the meeting does not count towards the quorum for the vote. The member's absence under these circumstances is called a recusal, not an abstention or an absence.

5.7 If an IEC of SIU (CT) member finds that he/she has a COI during the conduct of a research project approved by IEC of SIU (CT), he/she shall report the conflict to the IEC of SIU (CT) at the next IEC of SIU (CT) meeting.

5.8 At the beginning of each meeting, the IEC of SIU (CT) Chairperson will ask the members to disclose any COI concerning any of the items on the agenda. During the meeting, IEC of SIU (CT) member having conflict will disclose the existence of the conflict just before the review of the relevant item begins.

5.9 If the Chairperson has a conflict of interest for a particular project, this should be so declared and handled like any other member's conflict is handled. An acting Chair should be appointed for discussion in such a scenario.

5.10 When determination regarding existence of COI is uncertain, for an IEC of SIU (CT) member, he / she may consult the Chairperson / Member Secretary / additional Member Secretary (as applicable) with all the related information.

5.11 The IEC of SIU (CT) Chairperson has the final authority to decide whether a COI has been managed or eliminated appropriately for research participant protection.

5.12 The IEC of SIU (CT) shall not approve a research study proposal where a COI is not managed or eliminated.

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6. Management of CO – In case of a COI

6.1 IEC of SIU (CT) members will disclose the COI as discussed above
6.2 The concerned IEC of SIU (CT) members will not serve as a reviewer in case of the conflicted proposal/s
6.3 The IEC of SIU (CT) members will not influence the discussion and decision making of the concerned study by staying away during the IEC of SIU (CT) meeting.
6.4 IEC of SIU (CT) Member Secretary and the Secretariat will record the points related to disclosure and management of COI of IEC of SIU (CT) members in the IEC of SIU (CT) minutes.
6.5 IEC of SIU (CT) member with COI will not be able to vote.

7. Privacy and Confidentiality

The ICMR Guideline in its General Principles states the need of ensuring privacy and confidentiality whereby to maintain privacy of the potential participant, her/his identity and records are kept confidential and access controlled. However, under certain circumstances (suicidal ideation, homicidal tendency, HIV positive status, when required by court of law etc.) privacy of the information can be breached in consultation with the EC for valid scientific or legal reasons as the right to life of an individual supersedes the right to privacy of the research participant.

Violation of Privacy and Confidentiality could harm the participant physically, mentally, psychologically, financially and socially. It is the duty of the IEC of SIU (CT) members to ensure that the privacy and confidentiality of information that comes to them during the discharge of their duties. All investigators, experts and staff are enjoined to protect the privacy and confidentiality of all information that is a part of research and related activities. All the aforementioned individuals are required to sign an agreement to protect the privacy and confidentiality of all information that reaches them or they become aware during the discharge of their duties.

7.1 Agreement regarding maintenance of confidentiality

7.1.1 It is the responsibility of each IEC of SIU (CT) member, reviewing research projects or attending IEC of SIU (CT) meetings, to read, understand, accept and sign the agreement contained in the confidentiality form (annexure 3).
7.1.2 The staff of the secretariat will sign confidentiality agreement which should be filed with the IEC of SIU (CT) records (annexure 3).
7.1.3 The secretariat will obtain the signature of the HOI on the confidentiality form.
7.1.4 The secretariat will provide IEC of SIU (CT) members a photocopy of the confidentiality form for their records (duly signed and dated by them and HOI) and obtain acknowledgment of receipt of agreement.
7.1.5 The secretariat will keep the original copies of the signed agreements in the IEC of SIU (CT) office in the file entitled 'Confidentiality Agreement file' for members along with the CV of individual members.

8. References

8.1 National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, ICMR 2017.

8.2 Declaration of Helsinki, Revision of 2013, Fortaleza, Brazil.

Function	Name	Designation	Signature
Prepared by	**Dr. Manjiri Joshi**	**Head, Clinical Research Dept, SUHRC & SMCW**	
Reviewed by	**Dr. Ravindra Ghooi** **Dr T. Vijaya Sagar**	**Member, IEC** **Dean, SMCW**	
Approved by	**Dr. Raman Gangakhedkar**	**Chairman**	

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IEC for Clinical Trials, Bioavailability (BA) and Bioequivalence (BE) Studies	Title: Frequency of meetings	SOP No: A3: Frequency of meetings
	Version: 02	Preparation Date: 18 June 2021
	Effective Date:	Review Date:

Frequency of IEC of SIU (CT) Meetings

1. Purpose

This SOP defines the type and frequency of meeting of the IEC of SIU (CT) that need to be held, it also specifies the conditions in which expedited reviews, SAE Committee meetings may be conducted.

2. Scope

The SOP is applicable to the IEC of SIU (CT), and any sub committees thereof only.

3. Responsibility

The Chairperson and Member Secretary of the IEC of SIU (CT) are responsible to ensure that EC meetings are held at the required frequency.

4. Detailed Instructions

4.1 Type of Meetings

4.1.1 Full Board Meeting

Full board meetings require the quorum to be complete and are held to discuss agenda which is circulated at least 3 weeks prior to the meeting. These meetings are held physically, in the meeting room. In the pandemic conditions, prevailing currently meetings through video conferencing are permissible as per ICMR Guidance of 2020. In the normal circumstances only those members who are physically present in the meeting room may vote on any proposal. ICMR recommends that full board review be held in the following circumstances:

All research proposals presenting more than minimal risk that are not covered under exempt or expedited review should be subjected to full committee review, some examples are;

1. research involving vulnerable populations, even if the risk is minimal;
2. research with minor increase over minimal risk
3. studies involving deception of participants
4. research proposals that have received exemption from review, or have undergone expedited review/undergone subcommittee review should be ratified by the full committee, which has the right to reverse/or modify any decision taken by the subcommittee or expedited committee;
5. amendments of proposals/related documents (including but not limited to informed consent documents, investigator's brochure, advertisements, recruitment methods, etc.) involving an altered risk;
6. major deviations and violations in the protocol;
7. any new information that emerges during the course of the research for deciding whether or not to terminate the study in view of the altered benefit–risk assessment;
8. research during emergencies and disasters either through an expedited review/ scheduled or unscheduled full committee meetings. This may be decided by Member Secretary depending on the urgency and need;
9. prior approval of research on predictable emergencies or disasters before the actual crisis occurs for implementation later when the actual emergency or disaster occurs.

4.1.2 Expedited Review

Expedited reviews may be conducted and approvals granted under certain circumstances, these could be granted by the Chairperson and another member chosen for his/her expertise in the clinical domain. Expedited approvals are generally not granted for initial submissions in case of interventional studies. Observational and descriptive studies may be granted such approvals.

In case of interventional studies, periodic reviews, amendments, additional documents may be granted expedited approvals. ICMR recommends that those studies (or changes) that involve less than minimal risk to participants may be granted expedited approvals. ICMR recommendations in detail are as follows:

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1. Proposals that pose no more than minimal risk may undergo expedited review, for example;
2. research involving non-identifiable specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples;
3. research involving clinical documentation materials that are non-identifiable (data, documents, records);
4. modification or amendment to an approved protocol including administrative changes or correction of typographical errors and change in researcher(s);
5. revised proposals previously approved through expedited review, full review or continuing review of approved proposals;
6. minor deviations from originally approved research causing no risk or minimal risk;
7. progress / annual reports where there is no additional risk, for example activity limited to data analysis. Expedited review of SAEs/unexpected AEs will be conducted by SAE subcommittee; and
8. for multicentre research where a designated main EC among the participating sites has reviewed and approved the study, a local EC may conduct only an expedited review for site specific requirements in addition to the full committee common review.
9. research during emergencies and disasters (See Section 4.1.3 for further details)

4.1.3 Meetings during emergencies and disasters

The ICMR has provision for alternative methods to cope up with emergencies and disasters such as the current pandemic.

Research during humanitarian emergencies and disasters can be reviewed through an expedited review/scheduled/unscheduled full committee meetings and this may be decided by the Member Secretary on a case-to-case basis depending on the urgency and need. If an expedited review is done, full ethical review should follow as soon as possible.

Meticulous documentation and archiving are required to enable future application in similar situations.

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4.1.3.1 Suggestions to expedite the review process are given below:

1. Measures such as virtual or tele-conferences should be attempted when face-to face meetings are not possible.
2. In exceptional situations, preliminary research procedures including but not restricted to data/sample collection that are likely to rapidly deteriorate or perish may be allowed while the review process is underway.
3. Available protocol templates could be reviewed to expedite the process.
4. Re-review should be done if the emergency situation changes.
5. In situations where members of local ECs are unavailable due to the emergency, the ethics review may be conducted by any other recognized EC within India for initiating the study, until the local EC is able to convene its meeting. ECs should develop procedures to ensure appropriate and timely review and monitoring of the approved research. On a case-by-case basis, some protocols may require re-review as the emergency situation may change with time and circumstances.

The EC should closely monitor the conduct and outcome of research.

4.2 Frequency of Meetings

The IEC of SIU (CT) shall meet not less than 4 times a year, each meeting being spaced out reasonably. The frequency of SAE subcommittee meeting is not fixed but depends upon the need. The IEC of SIU (CT) should meet twice a year to actually audit trials being conducted under its approval.

5. References:

5.1 National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, ICMR 2017

5.2 New Drugs and Clinical Trial Rules 2019.

Function	Name	Designation	Signature
Prepared by	**Dr. Manjiri Joshi**	**Head, Clinical Research Dept, SUHRC & SMCW**	
Reviewed by	**Dr. Ravindra Ghooi** **Dr T. Vijaya Sagar**	**Member, IEC** **Dean, SMCW**	
Approved by	**Dr. Raman Gangakhedkar**	**Chairman**	

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Financial management of projects

1. Purpose

To describe the procedures related to financial matters, fees and financial management of the research studies by the IEC of SIU (CT) of SUHRC

2. Scope

This SOP will apply to all funded research studies submitted to the IEC of SIU (CT) and will include all the financial procedures related to the receipt of funds (from external source), and their utilization. This SOP will ensure that the funds provided by the sponsor do not act as an incentive for approval of studies reviewed by the IEC of SIU (CT). However, fees will be charged to the sponsors for review of the new study protocols or protocol amendments and for pre-site initiation activities.

3. Responsibility

It is the responsibility of accounts staff of IEC of SIU (CT) Secretariat to maintain study-wise financial record in terms of income and expenditure for review and inspection.

4. Detailed instructions

The following processes are involved in handling of finances –

4.1 Fees for IEC of SIU (CT) review, archival and additional processes

***The fees for reviewing various categories of research study proposals in Indian Rupees (INR): are given in the following table and they are non-refundable:

Sr. No	Category of Review	Industry	Other Sponsors
1	New protocol	60000	TBD on a case to case basis
2	Protocol Amendment	10000	TBD on a case to case basis
3	SAE review	15000	TBD on a case to case basis

* Refer to site SOP for archival of investigator's clinical trial documents.

All the above charges are excluding taxes. All taxes to be paid (by the sponsor) as per prevailing laws.

Some of the organizations exempt from payment of EC fees are – government institutes, educational institutes, NGO, charitable trusts, etc.

The study documents (eCRF, ICF, etc.) will be presently stored at the following address:

Ethics Committee Meeting Room MS office, Ground Floor, SUHRC Lavale, Pune: 412115

***The following are the charges of archival charges for 1 year of storage

Details	Charges in INR
Storage and archival charges	8000
GST @18% (or as applicable)	1440
Total charges (in INR)	9440

** All the above charges are applicable until further modifications.

4.2 Receipt of funds from the sponsor/ CRO –

Funds are received in the name of Institute name either by cheque or by wire transfer.

4.2.1 Cheque receipts: The PI/CRC submits the received cheques from the sponsor / CRO to the EC office detailing project code, project title, name of the principal investigator, % of tax deducted in the scheduled amount (without tax deduction in case of tax exemption*), service tax details, nature of receipt, and duration of work. Cheques with the details will then be forwarded by the accounts supervisor of research department to the accounts department of the hospital. The accounts department deposits the cheque(s) in the NHES account.

4.2.2 Wire transfer: The sponsor/CRO is required to send to the accounts staff of the Secretariat the NEFT form (annexure 1) within 2 working days from the date of actual payment. The same will then be forwarded to the accounts department for its perusal and records.

*Tax exemption certificate necessary

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The IEC of SIU (CT) Secretariat can receive funds (as applicable) under the following heads –

- Ethics committee processing fees,
- Pre-site initiation fees,
- Archival fees,
- Amendment fees,
- Milestone completion receipts,
- Any other study related receipts

It will be the responsibility of the PI /CRC to follow-up with the Sponsor / CRO regarding receipt of payments against the invoices generated, and ensure its receipt as per the credit period mentioned in the CTA / MoU. Research department will follow-up with the PI / CRC regarding receipt of payments from time-to-time.

4.3 Redrafting the budget details as specified in the MOU to the in-house budget format

The total budget provided by the sponsor (in discussion with the PI) will be redrafted in the components as in the Budget form (annexure 2) for implementation. The details of the budget as in the MOU will also be forwarded for review to the finance department for statutory finance related comments. The details of the test(s) to be performed at SUHRC and their frequency, requirement of CRC/RF, patient travel allowance/compensation, materials required, capital asset expenses (if any), and duration of study will be confirmed / modified in consultation with the PI. The final budget form will be (a) circulated to IEC of SIU (CT) members for discussion during IEC of SIU (CT) meeting, and (b) submitted to the finance department for vetting.

4.4 The disbursement of TA/compensation to the study participants and the investigations related vouchers will follow departmental procedures.

4.5 Creating a monthly sheet of income and expense

IEC of SIU (CT) Secretariat will prepare a monthly income-expenditure sheet for each study approved by the IEC of SIU (CT)(annexure 3). The sheet will be maintained by the Secretariat. For the period of 5 years after the study closeout It can be reviewed and inspected by the IEC of SIU (CT) members, Director Finance and authorized personnel from DCGI.

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4.6 Disbursing honorarium & TA/DA to EC members

4.6.1 The Secretariat office will requisition the TA/DA amount to the accounts department after approval from the Member Secretary. The amount will be disbursed to members on the day of the meeting with acknowledgment of receipt obtained. The acknowledgment receipt will be sent to the accounts department for their records.

4.6.2 The Secretariat office will inform the accounts dept. to release the honorarium charges for the EC members. The accounts dept. will issue the individual cheque(s) to the Secretariat. The cheques will then be handed over to the committee members either by courier or in person. Acknowledgement will be taken at the time of the meeting.

4.7 Disbursing SAE compensation amount to the participants

On receipt of notification regarding the amount of compensation to be given to the participant for the Serious Adverse Event sustained from the regulatory authority; the sponsor should be advised to make the required payment. If the sponsor does not send the sum within the stipulated period, of (no.) days following receipt of letter from DCGI (as per SAE compensation rules by DCGI), the hospital should make the payment. The amount paid may then be recovered from the sponsor/ CRO by SUHRC. The process for receipt of cheque / wired transfer and further action will be the same as that in 4.2.

4.8 Financial closure of the study and disbursing the PI/Co-PI component

The site close-out letter will be received by the EC Secretariat. The Member Secretary will acknowledge the copy and inform the accounts staff to forward the item-wise amount utilized/consumed in the project to PI for information and enquire about any pending financial transactions. PI will revert to Secretariat with the information and queries (if any); otherwise PI will approve the budget utilization report to effect financial closure of the project. After confirmation the Member Secretary will inform the accounts staff to forward the item-wise utilized/consumed report of the project to the finance-costing dept. for approval and advise final financial closure of the project & releasing the due PI/Co-PI component. Finance-costing dept. will share a copy of the final financial closure with the research dept. once the PI component is released.

(All the applicable taxes and charges will be implemented and paid by the sponsor)

4.9 Process for archival of documents

4.9.1 Following database lock / study completion, the Sponsor / CRO will inform the PI about date of site closure. PI will verify all the invoices raised and the settlement thus received with the research department. If all settlements have been done, confirmation towards site close-out will be informed to the PI by research department. In case of pending settlements, PI will have to ensure receipt of all payment(s) from the sponsor prior to close-out date.

4.9.2 PI will then confirm with the sponsor the date of site closure and request the sponsor / CRO to send the payment for archival of study documents as mentioned in clause 4.1. Period of archival will be as mentioned in the CTA / MoU or 5 years as per DCGI guidelines (whichever is longer). The archival fees will have to be sent by the sponsor prior to site close-out date.

4.9.3 Documents will be packed in the trunks in presence of PI (if available), CRC, one Secretariat member and study monitor designated by the sponsor/CRO.

4.9.4 Detailed list of archived study documents will be handed over to IEC of SIU (CT)Secretariat mentioning the period of archival. Research department will send the trunks to the archival site after labelling the trunk with the project code, PI name & date of archival.

4.9.5 A record of the archived documents will be maintained as a soft copy.

4.10 Process for generating invoice & payment receipt

4.10.1 For EC fees invoice: Following site visit and selection, sponsor will send a letter of confirmation to the PI. PI will forward the copy of the letter (soft or hard copy) the CRC to generate draft of Tax Invoice. CRC will forward the draft of tax invoice to the accounts supervisor, research department for verification.

4.10.2 For other study related invoice (Patient visit and trial expenses): Following a study monitoring visit, and confirmation of details from the trial monitor, CRC will prepare draft of tax invoice. The draft of tax invoice will be sent to the accounts supervisor, research department.

4.10.3 Verification of invoice: CRC/PI will verify the invoice within three working days of the receipt. This will be forwarded to finance department for re-verification. Finance department will revert within three working days with approval.

4.10.4 The invoice will be given to the PI for signature. Original copy of the invoice will be handed over to the PI and photo copy will be filed in the research department records.

4.10.5 Request towards generation of trial related invoice will be accepted only along with PI's authentication.

Function	Name	Designation	Signature
Prepared by	**Dr. Manjiri Joshi**	**Head, Clinical Research Dept, SUHRC & SMCW**	
Reviewed by	**Dr. Ravindra Ghooi** **Dr T. Vijaya Sagar**	**Member, IEC** **Dean, SMCW**	
Approved by	**Dr. Raman Gangakhedkar**	**Chairman**	

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Training of IEC of SIU (CT) Members

1. Purpose

In order to be updated on changes in ethics and regulations, investigators, members and staff of the IEC of SIU (CT) need to undergo training to keep them abreast with changes.

2. Scope

The need for training is absolute for all members of the IEC of SIU (CT), IEC staff, investigators, experts and other individuals who work in coordination with IEC of SIU (CT). New members joining the IEC should be trained, and if not trained they should provide evidence of training within 6 months of joining the EC.

3. Responsibility

The Chairperson and Member Secretary is responsible for ensuring that all members are trained on latest regulations and guidelines issued by the Central Drugs Standards and Control Organization (CDSCO), ICMR and other important organizations that issue such guidance.

4. Detailed Instructions

IEC of SIU (CT) works as per the recommendations and regulations of a number of organization, the documents that are regularly referred to and followed include, but are not limited to the following:

- Nuremberg Code 1948
- Declaration of Helsinki 1964
- CIOMS Guidelines 2001
- ICH GCP (E6R) 2016
- ICMR Guidelines 2017
- Medical Device Rules 2017
- New Drugs and Clinical Trial Rules 2019

Members of the IEC of SIU (CT) need to be trained in at least the following:

- ICH GCP (E6R) 2016
- ICMR Guidelines 2017
- New Drugs and Clinical Trial Rules 2019
- IEC of SIU (CT) SOPs

Members should attend at least two training sessions annually and produce certificates attesting their attendance of the same. These training could be organized by SIU, or other organizations in the city or elsewhere.

4.1 Training for IEC of SIU (CT) Members

An individual selected as a new member of the IEC of SIU (CT) may be required to attend one meeting as an 'Observer' before being inducted as a member of the IEC of SIU (CT). This will be decided from a case to case basis

4.1.1 Member secretary or an IEC of SIU (CT) member will provide introductory training in research ethics, GCP and SOPs to the new member.

4.1.2 IEC of SIU (CT) members including Chairperson and Member Secretary / additional Member Secretary will be encouraged to receive initial and continued education regarding the ethics and science of biomedical research, stem cell research by participating in a workshop, conference and/or e-training program as a delegate, faculty, facilitator, etc.

4.1.3 All IEC of SIU (CT) members must be conversant with ICMR Guidelines for Research involving Human Subjects 2017, New Drugs and Clinical Trials Rules, 2019, National guidelines for stem cell research and ICH-GCP guidelines.

4.1.4 IEC of SIU (CT) members will receive introductory training material in research bioethics and functioning of IEC of SIU (CT) (mainly via email) and will be exposed to ongoing opportunities for enhancing their capacity for ethical review. Training material circulated by the Member Secretary / additional Member Secretary will be discussed in the meetings and minuted.

4.1.5 Training of the IEC of SIU (CT) members in Research Bioethics

4.1.6 The IEC of SIU (CT) members will be encouraged to receive ongoing training by attending workshop at least once every year.

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4.1.7 The IEC of SIU (CT) may conduct workshops from time to time to impart training to the IEC of SIU (CT) members and Institutional faculty members.

4.1.8 The training program may be scheduled and spread over the year.

4.1.9 If the member is not able to attend the workshop, reading material will be provided to him, for him to keep himself updated

5. Records

IEC of SIU (CT) members are requested to submit their training certificates to the EC office, which shall maintain training records of all IEC of SIU (CT) members. The EC office shall maintain a copy of any training material used for in house trainings.

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Prepared by	**Dr. Manjiri Joshi**	**Head, Clinical Research Dept, SUHRC & SMCW**	
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Approved by	**Dr. Raman Gangakhedkar**	**Chairman**	

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IEC for Clinical Trials, Bioavailability (BA) and Bioequivalence (BE) Studies	Title: Procedure for Receipt of Applications	SOP No: B1: Procedure for Receipt of Applications
	Version: 02	Preparation Date: 18 June 2021
	Effective Date:	Review Date:

Procedure for Receipt of Applications

1. Purpose

The IEC of SIU (CT) processes a large number of applications, for new projects, amendments, additional documents, periodic reviews, SAE reports etc. This SOP lays down the procedure for their receipt and processing.

2. Scope

This SOP applies to the IEC of SIU (CT), its sub committees, and administrative staff who receive applications from any party, whether internal or external. This SOP covers documents mentioned below but is not limited to:

2.1 Submission of research projects and related documents for initial review of the protocol.

2.2 Resubmission of protocols / research projects with modifications / corrections.

2.3 Submission of protocol amendments and any other amendments.

2.4 Submission of written communications related to –

2.4.1 Continuing review of approved protocols

2.4.2 Study completion / termination

2.4.3 Protocol deviations / violations

3. Responsibility

The Member Secretary and the Chairperson are responsible for ensuring that all applications are received that are complete, and they are received in time. The schedule for receipt of documents and applications is laid down in this SOP and shall be followed at all times. In emergency situations the Chairperson may decide to waive some or all clauses of submission.

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4. Detailed Instructions

4.1 Receive submitted packages

The PI will submit a research proposal and related documents to the IEC of SIU (CT) office for review and decision under any of the following 5 sections within the specified time period:

4.1.1 Initial review application – Projects submitted for initial review should be submitted 21 days prior to the date of EC meeting. The date of EC meeting may be confirmed with the Secretariat. The study will not be discussed in the meeting in case of any document(s) pending submission.

4.1.2 Resubmission of protocols with corrections

4.1.3 Protocol amendment or amendments and any other amendments

4.1.4 Continuing review of approved protocols

4.1.5 Protocol completion / termination

The documents for 3, 4, and 5 are required to be submitted to the Secretariat office at least 21 days prior to the meeting. The documents will have to be organized by the concerned PI and then submitted to the office.

4.2 Verify contents of submitted package

The Secretariat will check the package for the receipt of following –

4.2.1 Maximum (5) copies of EC documents and 1 soft copy in a pen drive / email. The Secretariat will ensure that the application is complete in terms of required documents (if any essential document is not available a written explanation must be sought for committee to review)

4.2.2 Checklist will be filled, signed, and dated by the PI

4.2.3 Project submission application form and the budget form

4.2.4 Related documents necessary for initial review (*annexure*)

4.2.5 Check completeness of necessary information and put signature at all appropriate places in the application form submitted for initial review.

4.2.6 Notify the applicants, if a package is incomplete.

The package will be forwarded to CRC – EC operations, only when all the documents are received for EC review.

State clearly the items missing in the package on the Protocol submission/document receipt form.

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4.3 Details of essential documents to be submitted –

Use the checklist below to confirm whether all the ticked documents are submitted with the application.

4.3.1 Covering letter to Chairperson / Member Secretary / additional Member Secretary

4.3.2 Project submission form

4.3.3 Budget sheet for the proposed study

4.3.4 Investigator Brochure

4.3.5 Protocol

4.3.6 Patient information sheet and informed consent form with translations and back translations

4.3.7 Decision(s) of other Ethics Committees (if required / asked for)

4.3.8 Regulatory permissions (DCGI approval)

4.3.9 Valid GCP training certificate of all team members (as applicable)

4.3.10 Clinical trial agreement between the sponsor, PI, and the institute

4.3.11 Insurance policy (preferably with the policy document and not only the insurance certificate) for study participants indicating conditions of insurance coverage, date of commencement and date of expiry of the coverage of risk.

4.3.12 Indemnity policy clearly indicating the conditions of coverage, date of commencement and date of expiry of coverage.

4.3.13 Documentation of clinical trial registration (if applicable)

4.3.14 Any other document as required by the IEC of SIU (CT).

4.4 Completion of the submission process –

The Secretariat will –

4.4.1 Stamp, sign & date of receipt on the cover letter confirming receipt of the documents.

4.4.2 Make a photocopy of the completed document receipt form (*annexure*) and handover the same to the PI for their records. Retain the original form (*annexure)* and checklist for IEC of SIU (CT) records.

4.4.3 Ensure submission of correct number of hard copies (as stipulated by the IEC of SIU (CT) Secretariat)

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4.4.4 Store the hard copies and soft copy of the research project. The hard copies will be stored in locked cupboards in IEC of SIU (CT) office and soft copy of IEC of SIU (CT) submission form /study protocol accepted by email will be saved on IEC of SIU (CT) computer and as back up on the server.

4.4.5 The project file will be numbered as serial number/ Year / Principal Investigators initials code/ Type e.g. 520-09-VN (SP-DT) will indicate – 520 as serial no of project, 09 – year, VN as code of PI (e.g.: Dr. V. Natrajan) and MRC is for type of project. Type of project can be as follows:

SP-DT	Industry sponsored Drug studies/ trials
SP	Industry / Non-industry Sponsored Other studies

4.4.6 All correspondence for the projects should quote full code and complete title of the study project.

4.4.7 Store the received packages, which include original protocol file and copies of the protocol to be distributed for review.

4.5 Dispatch the received packages –

4.5.1 The Secretariat will prepare sets of protocol package as per EC member list and related documents with checklist and send the same to all the members along with the assessment form for initial review to the lead discussant(s), at least (14) days prior to the due date of the meeting.

4.5.2 The original protocol file and documents will be stored in a designated storage area in the IEC of SIU (CT) office.

4.5.3 The assessment forms from the lead discussant(s) will be handed over to the Secretariat on the day of the meeting.

4.6 Resubmission of protocols with corrections as per IEC of SIU (CT) suggestions

4.6.1 For resubmitted protocol, the PI will submit one copy of the amended protocol and related documents along with justification for amendment. In the revised submission; sections which have undergone amendment will have to be clearly highlighted.

4.6.2 The IEC of SIU (CT) Secretariat will verify the completeness of the submission and reconfirm that the copy contains the modification highlighted with respect to the earlier protocol.

4.6.3 The IEC of SIU (CT) Secretariat will perform the steps mentioned in the initial review application. The protocol related documents which do not require to be changed and are already submitted to the IEC of SIU (CT) during initial review need not be submitted again.

4.6.4 The modified protocol and related documents will be submitted to the Member Secretary / additional Member Secretary.

4.6.5 The Member Secretary / additional Member Secretary will decide whether the protocol will be circulated to all members for approval preferably via email or will the review be carried out by one or more member(s) as per the minutes of the meeting that had discussed the study earlier.

4.7 Research protocol amendments and other study related documents

4.7.1 The PI will submit hard copies (as stipulated by the IEC of SIU (CT) Secretariat) of the protocol amendments or any other study related documents to the IEC of SIU (CT) Secretariat along with the summary and justification of the amendment(s) in the document(s).

4.7.2 The IEC of SIU (CT) Secretariat will verify the completeness as per checklist / summary of the contents of submitted package as mentioned in the covering letter.

4.7.3 The PI will highlight the modification/s in the amendment, along with a summary of changes and whether these changes would entail changes in the ICF.

4.7.4 The Member Secretary in consultation with Chairperson will decide whether to:

4.7.4.1 Carry out an expedited review in case of minor administrative amendment.

4.7.4.2 Table the proposal for discussion at the full board meeting.

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4.8 Annual continuing reviews of approved protocols

4.8.1 The IEC of SIU (CT) Secretariat may send reminders for annual reports to individual PIs, well in advance before the expiry date of approval, which usually is one year from the date of releasing project approval letter.

4.8.2 The IEC of SIU (CT) will receive a copy of annual study report/ continuing review report in the prescribed format and related documents for the approved protocol.

4.8.3 The IEC of SIU (CT) Secretariat will verify the completeness of the continuing review application form progress report / request letter for extension of approval of the project. The IEC of SIU (CT) Secretariat will sign and date the documents.

4.8.4 The progress or continuing review report will be tabled in the full board meeting of IEC of SIU (CT).

4.9 Protocol completion

4.9.1 The IEC of SIU (CT) Secretariat may send reminders for completion report to Individual PI.

4.9.2 The IEC of SIU (CT) will receive a copy of study completion report in the prescribed format

4.9.3 The IEC of SIU (CT) Secretariat will verify the completeness of the study completion report form filled by the PI.

4.9.4 The study completion report will be tabled in the full board meeting of IEC of SIU (CT).

4.9.5 The IEC of SIU (CT) Secretariat will inform the termination of a clinical trial within 30 working days to the DCGI with detailed reasons for such termination.

4.10 Emergency Situations

The current Covid 19 pandemic has taught us that there could be similar emergency situations which require special handling. Since it is virtually impossible to foretell the sort of emergency that may befall, the Chairperson has the authority to take decision in good faith, about receipt of documents or applications and waiver for submissions.

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4.11 Reference

4.11.1 International Council on Harmonisation, Guidance on Good Clinical Practice (ICH GCP) 1996 Retrieved from - *http://www.ich.org/LOB/media/MEDIA482.pdf*
4.11.2 New Drugs and Clinical trials Rules, 2019 [GSR 227 (E) – 19 Mar 2019

Glossary

Investigator's Brochure: The Investigator's Brochure (IB) is a compilation of the clinical and non-clinical data on the investigational product(s) that are relevant to the study of the product(s) in human subjects

Study Protocol: A document that describes the objective(s), design, methodology, statistical considerations and organization of a trial

Function	Name	Designation	Signature
Prepared by	**Dr. Manjiri Joshi**	**Head, Clinical Research Dept, SUHRC & SMCW**	
Reviewed by	**Dr. Ravindra Ghooi** **Dr T. Vijaya Sagar**	**Member, IEC** **Dean, SMCW**	
Approved by	**Dr. Raman Gangakhedkar**	**Chairman**	

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Initial review of submitted Protocol

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how the IEC of SIU (CT) members will review an initially submitted protocol for approval using the assessment form for initial review.

2. Scope

This SOP applies to the review and assessment of all protocols submitted for initial review and approval of the IEC of SIU (CT). The comments made during discussion and deliberation on a specific protocol will be recorded in the minutes of the meeting. The decision reached by the IEC of SIU (CT) will be communicated to the PI.

3. Categorization of protocols (Annexure)

The Secretariat shall screen the proposals for their completeness. Member Secretary, depending on the risk involved in the research proposals, will categorize them into three types, viz.

3.1 Initial review

3.2 Expedited review

3.3 Exemption from review (Waiver).

An investigator is not authorized to categorize his/her protocol, but may request the EC to treat the protocol as per one of the above categories.

4. Responsibility

4.1 The Member Secretary / additional Member Secretary is responsible, after categorization of the studies, to forward the studies to the Secretariat.

4.2 The IEC of SIU (CT) Secretariat is responsible for creation of a study specific file, distribution of the packages to the IEC of SIU (CT) members along with study assessment

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forms to the lead discussants for review (if the study is categorized for full board review), and communicate the review decisions to the investigators.

4.3 IEC of SIU (CT) members (including Member Secretary / additional Member Secretary) will be responsible for reviewing the research protocols and related documents within the given time frames.

4.4 It is the responsibility of all the lead discussant(s) to fill the assessment form along with comments and recommendations after reviewing study protocol.

4.5 The IEC of SIU (CT) members are expected to attend and participate actively in the discussion at the full board meeting.

4.6 The Member Secretary / additional Member Secretary is responsible for setting up the full board meeting with the assistance of the Secretariat.

4.7 The IEC of SIU (CT) Secretariat is responsible for recording and filing the IEC of SIU (CT) decision, relevant points and deliberations about individual protocols, including the reasons for decisions taken.

4.8 The Chairperson is responsible to sign and date the decision in the IEC of SIU (CT) Decision Form (*annexure)*.

5. Detailed instructions

5.1 Distribution of the project documents

5.1.1 The Secretariat receives documents submitted by the PI and checks it for completeness as per checklist (*annexure*) and acknowledges receipt of documents to the PI.

5.1.2 The Secretariat will then sort the protocol package and circulate the hard copy (via courier/ personal delivery) and/or soft copy (via email) of the study related documents along with the study assessment form to lead discussant(s) (*annexure*). Members will acknowledge receipt of copies of protocol.

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5.2 Assigning Primary Reviewers

Member Secretary, IEC of SIU (CT) will assign (no.) Primary Reviewers to each research protocol. A Primary Reviewers is a member of IEC of SIU (CT) responsible for a detailed review of the assigned protocol

5.2.1 A Primary Reviewer is informed preferably 10 days prior to the meeting through the tentative agenda. In case the lead discussant is not in a position to review due to some reason; he/she should inform the Member Secretary IEC of SIU (CT) at the earliest, so that the research protocol(s) can be assigned to another member.

5.2.2 In the event of his/her absence, a Primary Reviewer can send written comments (via email or hard copy) on the research protocol to the Member Secretary which will be tabled and discussed during the meeting. However, a final decision on the research protocol will be arrived at, by a broad consensus at the end of discussion among attending members and not solely based on the written comments.

5.2.3 It is the responsibility of the assigned Primary Reviewers to review the research protocols assigned to them thoroughly, offer their observations, comments and recommendations regarding decisions to the IEC of SIU (CT) during the meeting and return all research protocols to the Secretariat on the day of the meeting or destroy the documents at his/her end and inform accordingly. Additionally, members may raise appropriate queries and send via email for discussion during the meeting.

5.3 Receipt and verification of contents of protocol package

5.3.1 IEC of SIU (CT) members will verify all the contents of the package.

5.3.2 IEC of SIU (CT) members will notify the Secretariat if any document(s) is missing and will notify well in advance if the member is unable to attend the meeting.

5.3.3 The members must return the packages to the IEC of SIU (CT) Secretariat on the day of the scheduled meeting. In case an IEC of SIU (CT) member is not in a position to attend the scheduled meeting, the responsibility of returning of packages would that be of the concerned IEC of SIU (CT) member. A member may securely destroy the protocol package at his/her end and inform the Secretariat accordingly.

6. Elements of review

The primary task of the IEC of SIU (CT) is to review research proposals and their supporting documents with special attention given to the informed consent process, documentation, and the suitability and feasibility of the protocol. IEC of SIU (CT) will take into account the requirements of applicable laws and regulations.

The following will be considered, as applicable:

- Scientific design and conduct of the study
- Risks and potential benefits
- Selection of study population and recruitment of research participants
- Inducements, financial benefits, and financial costs
- Protection of research participants' privacy and confidentiality
- Community considerations
- Assess qualifications of investigators and adequacy of study sites
- Disclosure or declaration of potential conflicts of interest

6.1 Scientific design and conduct of the study

6.1.1 The appropriateness of the study design in relation to the objectives of the study

6.1.2 The statistical methodology (including sample size calculation), and the potential for arriving at sound conclusions with the smallest number of research participants

6.1.3 Steps to be taken if research participants voluntarily withdraw during the course of the research

6.1.4 The adequacy of provisions made for monitoring and auditing the conduct of the research, the adequacy of the site, including the supporting staff, available facilities, and emergency procedures.

6.1.5 The manner in which the results of the research will be reported and published

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6.2 Risks and potential benefits

6.2.1 The justification of predictable risks and inconveniences weighed against the anticipated benefits for the research participants and the concerned communities

6.2.2 The justification for the use of control arms; criteria for prematurely withdrawing research participants

6.2.3 Any plans to withdraw or withhold standard therapies for the purpose of the research, and the justification for such action

6.2.4 Criteria for suspending or terminating the research as a whole.

6.3 Selection of study population and recruitment of research participants

6.3.1 The characteristics of the population from which the research participants will be drawn should be equitable, and unbiased with special attention in case of vulnerable population (including gender, age, literacy, culture, economic status, and ethnicity) (Refer APP2/V4)

6.3.2 IEC of SIU (CT) members will review the strategies of recruiting participants in the study in order to avoid inducement to patients to participate in the clinical trial. The PI may be asked to present in brief on how he/she plans on enrolling patients. The following different ways may be used but will not be restricted to –

6.3.2.1 Advertisement within SIU,

6.3.2.2 Flyers within the institute / other medical institutions,

6.3.2.3 Referrals from other hospitals / satellite clinics, etc.

6.3.2.4 Notice in the clinic

6.3.2.5 Search in database

6.3.2.6 Staff or relatives (vulnerable population), etc.

6.3.3 EC members may review the screening log of participants to ensure equitable distribution of participants in the study.

6.3.4 Participation in the study is voluntary

6.3.5 The means by which initial contact and recruitment is to be conducted

6.3.6 The means by which full information is to be conveyed to potential research participants or their representatives

6.3.7 Inclusion criteria for research participants

6.3.8 Exclusion criteria for research participants

6.3.9 Students or staff recruitment in research (Ref. APP1/V4)

6.4 Inducements, financial benefits, and financial costs

6.4.1 Description of any plans to make the study product available to the research participants following the research; a description of any financial costs to research participants (Refer APP3/V4)

6.4.2 Rewards and compensations for research participants (including money, services, and/or gifts)

6.4.3 Provisions for compensation/treatment in the case of injury/disability/death of a research participant attributable to participation in the research (Refer GSR 227(E) New drugs and clinical trials rules).

6.5 Protection of research participants' privacy and confidentiality

6.5.1 Arrangements, if appropriate, for informing the research participant's general practitioner or family doctor, including procedures for seeking the participant's consent to do so

6.5.2 Insurance and indemnity arrangements

6.5.3 A description of the persons who will have access to personal data of the research participants, including medical records and biological samples

6.5.4 The measures taken to ensure the confidentiality and security of personal information concerning research participants

6.6 Community considerations

6.6.1 Impact and relevance of the research on the local community and on the concerned communities from which the research participants are drawn

6.6.2 Steps taken to consult with the concerned communities during the course of designing the research

6.6.3 Influence of the community on the consent of individuals

6.6.4 Proposed community consultation during the course of the research

6.6.5 Extent to which the research contributes to capacity building, such as the enhancement of local healthcare, research, and the ability to respond to public health needs

6.6.6 A description of the availability and affordability of any successful study product to the concerned communities following the research

6.6.7 The manner in which the results of the research will be made available to the research participants and the concerned communities

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6.7 Assess qualifications of investigators and adequacy of study sites

6.7.1 Suitability of the investigators' qualifications and experience for the proposed study

6.7.2 Investigator's knowledge about the existing rules and regulations of the safety of the patient, ICH-GCP guidelines, and Schedule Y.

6.7.3 Medical care to be provided to research participants during and after the course of the research

6.7.4 Adequacy of medical supervision and for the research participants

6.7.5 Criteria for extended access to, the emergency use of, and/or the compassionate use of study products

6.8 Informed consent process

The IEC of SIU (CT) member will consider the following criteria when performing the review of the Informed Consent Document

6.8.1 Voluntary, non-coercive recruitment, participation/ withdrawal

6.8.2 Procedures for obtaining informed consent

6.8.3 Contents of the patient information sheet - title, objective, study design, and procedures

6.8.4 Contents and language of the informed consent document

6.8.5 Translation of the informed consent document in the local languages

6.8.6 Language used – plain and easy to understand by general public

6.8.7 Contact persons with address and phone numbers for questions about research participants rights and study or injury

6.8.8 Privacy and confidentiality

6.8.9 Risks and discomforts – physical / mental / social

6.8.10 Alternative treatments

6.8.11 Benefits – to participants, community, institution, and society

6.8.12 Compensation for participation: (whether it will act as undue inducement)

6.8.13 Involvement of vulnerable participants

6.8.14 Provisions for medical/ psychosocial support, if required

6.8.15 Treatment for study related injuries

6.8.16 Compensation for study-related injuries – disability, death: as per applicable local regulations

6.8.17 Use of biological materials

6.8.18 Check provision for signatures with dates of participant, person conducting informed consent discussion, investigator, and witness

6.8.19 Provision for audio-visual recording of consent process in case of regulatory drug trials

7. Use of study assessment forms

7.1 The assessment form is designed to standardize the review process.

7.2 The study assessment form helps to ensure that all elements of research protocol are reviewed and are accordingly documented during the discussion / meeting study assessment form template (*annexure*)

7.3 If the comments are received as soft copy or are communicated verbally during the meeting, these will be collated for discussion at the meeting and hence noted in the minutes of the meeting.

7.4 Members may also use electronic platform to review the study and offer comments which may be discussed during the meeting.

Note: **The completed assessment form is the official record of the opinions expressed by the** IEC of SIU (CT) **for the specific protocol**

8. References

8.1 World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000) Retrieved from- *www.who.int/tdr/publications/publications/*
8.2 International Council on Harmonisation, Guidance on Good Clinical Practice (ICH GCP) 1996 Retrieved from- *http://www.ich.org/LOB/media/MEDIA482.pdf*
8.3 Cavazos N., Forster D., and Bowen A.J., Ethical Concerns in Placebo-controlled studies: An Analytical Approach, Drug Information Journal 36(2) 2002: pgs 249-259, via WIRB documents
8.4 New drugs and clinical trial rules [GSR 227(E)] – 19 Mar 2019

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Glossary

Document: Document may be of any forms, e.g., paper, electronic mail (e-mail), faxes, audio or video tape, etc.

Pre-clinical study: Animal and *in vitro* studies provide information on possible toxicities and mechanisms of action, and starting doses for human studies

Phase I studies: Initial introduction of an investigational new drug (IND) into humans, studies designed to determine the metabolism and pharmacological actions of drugs in humans, and studies designed to assess the side effects associated with increasing doses

Phase II study: A study of drug metabolism, structure-activity relationships, and mechanism of action in humans, as well as studies in which investigational drugs are used as research tools to explore biological phenomena or disease processes

Phase III study: A study expands controlled and uncontrolled trials performed after preliminary evidence suggesting effectiveness of the drug has been obtained. They are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling

Phase IV study: A study that seeks to expand an approved medication's use into a new population, new indication, or new dose

Study Assessment Form: An official record that documents the protocol review process

Vulnerable subjects: A vulnerable category of subjects includes children, prisoners, pregnant women, handicapped or mentally disabled persons, refugees, displaced persons and economically or educationally disadvantaged persons, who are likely to be vulnerable to coercion or undue influence.

Minimal Risk: It means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. However, in some cases like surgery, chemotherapy or radiation therapy, greater risk would be inherent in the treatment itself, but this may be within the range of minimal risk for the research participant undergoing these interventions since it would be undertaken as part of current everyday life. **Example for minimal risk:** A retrospective review of patient case records to determine the incidence of disease/ recurrence of disease.

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Less than minimal risk: Research, in which there is no known physical, emotional, psychological, or economical risk to the study participants. This research qualifies as exempt if it does not involve special populations (i.e., minors, prisoners, pregnant women, etc.)

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Reviewed by	**Dr. Ravindra Ghooi** **Dr T. Vijaya Sagar**	**Member, IEC** **Dean, SMCW**	
Approved by	**Dr. Raman Gangakhedkar**	**Chairman**	

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IEC for Clinical Trials, Bioavailability (BA) and Bioequivalence (BE) Studies	Title: Expedited Review of submitted protocol	SOP No: C1.1: Expedited Review of submitted protocol
	Version: 02	Preparation Date: 18 June 2021
	Effective Date:	Review Date:

Expedited review of submitted protocol

1. Purpose

The purpose of this SOP is to describe how members of the IEC of SIU (CT) will perform an expedited review on a new research study protocol / protocol amendment that meets criteria of expedited approval.

2. Scope

This SOP applies to the review and approval of research protocols on expedited basis, when requested for the PI. The PI should also give the reasons for requesting an expedited approval.

3. Categorization of protocols

A PI may request for expedited review of his/her protocol and Member Secretary, depending on whether the proposal meets the criteria for expedited approval, may consult the Chairperson and grant the PI's request. This SOP describes the process of categorization of proposals for expedited review and the process in detail.

Expedited review may be conducted, as recommended by the ICMR in its guidelines of 2017, under the following conditions:

3.1 proposals that pose no more than minimal risk may undergo expedited review, for example;

3.2 research involving non-identifiable specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples;

3.3 research involving clinical documentation materials that are non-identifiable (data, documents, records);

3.4 modification or amendment to an approved protocol including administrative changes or correction of typographical errors and change in researcher(s);

3.5 revised proposals previously approved through expedited review, full review or continuing review of approved proposals;

3.6 minor deviations from originally approved research causing no risk or minimal risk;

3.7 progress/annual reports where there is no additional risk, for example activity limited to data analysis. Expedited review of SAEs/unexpected AEs will be conducted by members of the IEC of SIU (CT) designated for the purpose by the Chairperson.

3.8 for multicentre research where a designated main EC among the participating sites has reviewed and approved the study, a local EC may conduct only an expedited review for site specific requirements in addition to the full committee common review.

3.9 research during emergencies and disasters (See Section 12 ICMR Guidelines for further details).

4. Detailed Instructions

4.1 After categorization, of proposals the member secretary forwards the submitted document(s) to the Chairperson.

4.2 In case the Member Secretary is not sure of the categorization and the appropriateness of a proposal for expedited approval, he/she may consult the Chairperson before deciding on the type of review.

4.3 The Secretariat is responsible for creation of a study specific file, distribution of the packages along with study assessment forms / amendment related documents to designated members for review and communicate the decision to the PI.

4.4 Chairperson of IEC of SIU (CT) designates members for reviewing the research protocols and related documents / amendments on expedited basis within a timeframe decided by the Chairperson.

4.5 The designated members IEC of SIU (CT) will fill the study assessment forms / decision forms along with comments and recommendation after reviewing each study protocol / amendment document.

4.6 The designated member of the IEC of SIU (CT) records the decision on the review and conveys it to the Member Secretary and Chairperson.

4.7 In case the proposal is approved on an expedited basis, a letter of approval is sent to the PI. If the proposal is not approved, the proposal is taken up for full board review and the PI is informed accordingly. If the designated members recommend some changes, the same should be informed to the PI for compliance and resubmission.

4.8 The Chairperson of the IEC of SIU (CT) is responsible to sign and date the decision of the expedited review, following a clear recommendation signed by the designated member for expedited review.

4.9 The expedited review should not take longer than two weeks, from the date of receipt of the research protocol / amendment.

4.10 The minutes of the expedited review subcommittee meeting should be ratified in the next regular full board meeting

5. References

5.1 ICMR Ethical Guidelines for Biomedical research on Human Participants, ICMR (2017) - http://www.icmr.nic.in/ethical_guidelines.pdf
5.2 International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996- *http://www.ich.org/LOB/media/MEDIA482.pdf*
5.3 WHO Operational Guidelines for Ethical Review Committee that Review Biomedical Research (Geneva 2000) - *www.who.int/tdr/publications/publications/*

Glossary

Document: Document may be in any form, e.g., paper, electronic mail (e-mail), faxes, audio or video tape, etc.

Expedited review/meeting: A review process by members of the IEC of SIU (CT) and IEC of SIU (CT) subcommittee, designated by the Chairperson, who then report the decision to the Chairperson. The outcome of the expedited review is conveyed to the IEC of SIU (CT) members at the next meeting of the committee. An expedited review is an accelerated review for minor changes to the approved protocol, for research proposal with minimal risk and documents of minor nature.

Function	Name	Designation	Signature
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IEC for Clinical Trials, Bioavailability (BA) and Bioequivalence (BE) Studies	Title: Exemption from ethics review of research studies	SOP No: C1.2: Exemption from ethics review of research studies
	Version: 02	Preparation Date: 18 June 2021
	Effective Date:	Review Date:

Exemption from ethics review of research studies

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe the process of exemption from ethics review, of research projects that do not require a review or approval. This procedure is designed to standardize the process of exemption.

2. Scope

This SOP applies to all the protocols submitted with a request for exemption from review by the IEC of SIU (CT). The specific points in the exemption form should guide the Member Secretary to determine whether the protocol qualifies for exemption from IEC of SIU (CT), review. The decision should be taken by the Member Secretary in consultation with the Chairperson and should be informed to the members in the forthcoming IEC of SIU (CT) meeting.

3. Responsibility

PI may request for waiver of EC review, it is the responsibility of the Member Secretary to decide on the request in consultation with the Chairperson. The IEC of SIU (CT), Secretariat is responsible for recording and filing the decision including the reasons for that decision. The Chairperson must sign and date letter conveying the decision to the investigator.

4. Detailed instructions for the IEC secretariat:

4.1 Receive the exemption from review application form (annexure), along with the protocol and other documents submitted by the investigators.

4.2 Acknowledge the submitted documents.

4.3 Hand over the received documents to the Member Secretary/Chairperson, IEC of SIU (CT).

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5. Determine protocols eligible for exemption from review

The IEC Member Secretary will determine whether a protocol qualifies for exemption from review based on criteria explained in the ICMR Guideline. The following categories of proposals with less than minimal risk, where there are no linked identifiers qualify for such an exemption:

5.1 research conducted on data available in the public domain for systematic reviews or meta-analysis;

5.2 observation of public behaviour when information is recorded without any linked identifiers and disclosure would not harm the interests of the observed person;

5.3 quality control and quality assurance audits in the institution;

5.4 comparison of instructional techniques, curricula, or classroom management methods;

5.5 consumer acceptance studies related to taste and food quality; and

5.6 public health programmes by Govt agencies such as programme evaluation where the sole purpose of the exercise is refinement and improvement of the programme or monitoring (where there are no individual identifiers).

5.7 Research not involving use of humans as participants, in that though humans are involved, they are not subject to any intervention or are at not at any risk whatsoever.

6. Exemption Process

6.1 If the protocol and related documents satisfy the criteria of exemption, the Member Secretary in consultation with the Chairperson will review the project and the exemption form.

6.2 The Member Secretary records the decision on the exemption form.

6.3 The Secretariat communicates the decision to the investigator.

6.4 The Member Secretary informs the members of IEC of SIU (CT) about the decision in the next full board meeting and minute it in the meeting notes.

6.5 In case the protocol does not fit in the criteria of exemption, the Member Secretary / Chairperson may keep the application for review and discussion at the full board meeting (PI will be requested to submit all documents as required for the full board review).

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7. Communication between the IEC of SIU (CT) and the investigator

The decision regarding request for exemption from review, signed by the Chairperson/ Member Secretary of IEC of SIU (CT), will be forwarded by the secretariat to the principal investigator within 14 days after the decision regarding the exemption is taken.

8. References

8.1 ICMR's National Ethical Guidelines for Biomedical Research Involving Human Participants, ICMR (2017) - *http://www.icmr.nic.in/ethicalguidelines.pdf*

8.2 WHO Operational Guidelines for Ethical Review Committee that Review Biomedical Research (Geneva 2000) - *www.who.int/tdr/publications/publications/*

Glossary

Exemption from review: A research study is said to be exempt from review when it does not require the Ethics Committee approval for its conduct

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Approved by	**Dr. Raman Gangakhedkar**	**Chairman**	

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Studies involving Vulnerable Populations

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe procedures to review proposals involving vulnerable populations. The SOP provides clear, unambiguous instructions so that the activities of IEC of SIU (CT) are conducted in accordance with Indian laws and relevant, National and International Guidelines in protecting the vulnerable.

2. Scope

This SOP covers the policies and procedures applied to all research submitted to the IEC of SIU (CT) and which involves vulnerable population. Vulnerable population includes those defined as vulnerable by the ICMR Guideline 2017 and the New Drug and Clinical Trial Rules 2019.

3. Responsibility

3.1 It is the responsibility of the Member Secretary with assistance from Secretariat of IEC of SIU (CT) to maintain up-to-date tools, like checklists, for review of research pertaining to vulnerable groups based on new and evolving applicable regulations and guidelines.

3.2 IEC of SIU (CT) Chairperson/ Member Secretary are responsible for ensuring that IEC of SIU (CT) members are well versed in new and evolving regulations and guidelines pertaining to vulnerable populations, through regular training programmes.

3.3 The Chairperson/Member Secretary is responsible for selecting experts with appropriate expertise to and experience of working with vulnerable population, and for bringing them on board. Experts will be selected from a panel with the IEC of SIU (CT), they will sign a CDA before initiating the review.

3.4 Chairperson IEC of SIU (CT) is responsible for conducting appropriate review of research planned for vulnerable populations, including an assessment of potential for coercion, in consultation with any appropriate experts and resources as described in this SOP.

4. Responsibility of Secretariat

4.1 Maintain a list of experts with their CVs,

4.2 Maintain on file the updated checklist which conforms to applicable regulations and guidelines.

4.3 Document review of risk assessment in IEC of SIU (CT) minutes for the protocols involving vulnerable population.

4.4 Provide appropriate checklist as per the population in study to the investigator.

5. Responsibility of reviewers:

5.1 Members of IEC of SIU (CT) will review the protocol and the informed consent document or the assent form.

5.2 Members will take the advice of the expert, if appointed, on all decisions regarding vulnerable population

5.3 Members are responsible for verifying, and reviewing the research protocol pertaining to vulnerable population using relevant study assessment form and checklist

5.4 Members are responsible for conducting appropriate review of research planned for vulnerable population including an assessment of potential for coercion, in consultation with any appropriate experts and resources as described in this SOP.

5.5 The suggestions that are discussed and agreed upon by the IEC of SIU (CT) members present at the meeting will be sent to the PI.

5.6 The discussion will be documented in the minutes of the meeting.

5.7 The Member Secretary / additional Member Secretary will ensure that the recommended comments have been incorporated in the revised protocol and the informed consent document or assent form and other related documents.

5.8 Ensure that the Informed Consent process is recorded by Audio and video in case of clinical trials of NCEs or NBEs involving vulnerable participants.

5.9 Ensure that in case of trials on patients with HIV, Leprosy, no video recording is made, but only an audio recording of the Informed Consent process is recorded as per rules.

6. Definition and Mandate

6.1 Definition:

Vulnerable participants – Vulnerable persons are those who are relatively (or absolutely) incapable of protecting their own interests. More formally, they may have insufficient power, intelligence, education, resources, strength, or other needed attributes to protect their own interests. Individuals whose willingness to volunteer in a research study may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate may also be considered vulnerable. Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental, and nursing students, pregnant women, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces, and persons kept in detention. Other vulnerable persons include patients with incurable diseases, people in nursing homes, unemployed or impoverished people, patient's in emergency situations, ethnic minority groups, homeless people, nomads, refugees, minors, and those incapable of giving consent. This list may not be exhaustive as there may be circumstances in which other groups are considered vulnerable, women for example, in an orthodox patriarchal society.

6.2 Mandate

Section 2 (g) of Third Schedule of NDCTR lists down conditions for Audio-visual recording of consent process.

7. Detailed instructions

Reviewing the protocol involving vulnerable population

The protocol should be reviewed keeping in mind the following points when it concerns research that involves groups that could be potentially vulnerable to coercion

7.1 Can the research be performed in any other non-vulnerable participants?

7.2 Is there justification to use vulnerable population?

7.3 Are there measures to protect autonomy, rights and welfare of participants

7.4 Risk/benefit determination with respect to vulnerability

7.5 Bearing unequal burden in research.

Members of the IEC of SIU (CT) or secretariat who would be dealing with such protocols should be well versed with the potential harm or risk to such a population participating in the study.

8. Approval of the protocol

The final version of the protocol along with the appropriate checklist.

Wherever necessary the approval of the IEC of SIU (CT) should state that in future if the vulnerability status of the participant changes for e.g.: unconscious patient gaining consciousness, there should be an amendment made in the protocol and ICD and resubmitted to the IEC of SIU (CT) for reconsideration and approval. The participant should be re-consented and reconsidered for eligibility for study participation.

Glossary

Pregnant women: Pregnancy encompasses the period of time from implantation until delivery. A woman shall be assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.

Foetus: Foetus means the product of conception from implantation until delivery.

Viable foetus: Viable, as it pertains to the neonate, means being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration.

Non-viable foetus: Nonviable neonate means a neonate after delivery that, although living, is not viable (maintains heartbeat and respiration).

Neonate: Neonate means a new-born.

Mentally impaired persons: Mentally incapable to give consent due to the situation /condition Situational vulnerability Disasters create vulnerable persons and groups in society, particularly so in disadvantaged communities,

Harm: is a negative safety or health consequence; any detrimental effect of a significant nature

Risk: "chance"/probability that harm can occur

9. References

9.1 Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants (Geneva 2011) - www.who.int/...guideline.../operational-guidelines-ethics-biomedical-.

9.2 International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 2016.

9.3 ICMR's National Ethical Guidelines for Biomedical Research Involving Human Participants, ICMR (2017)

9.4 New Drugs and Clinical Trial Rules 2019.

9.5 Good Clinical Practices for Clinical Research in India http://cdsco.nic.in/html/GCP.htm

9.6 World Medical Association Declaration of Helsinki, http:// www.wma.net/en/30publications/10policies/b3/

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Risk Benefit Analysis

1. Purpose

Research activities carry some amount of risk and may result in benefits to the participants, or other patients or the community. It is necessary to analyse the risk benefit ratio before approving or commencing any research. This SOP describes a process to evaluate and balance the risks and expected benefits.

2. Scope

Risk benefit analysis is required to be carried out for any research undertaken in SIU or approved by the IEC of SIU (CT). The research conducted by staff, students, associates of SIU is all covered by this SOP, as is any external research reviewed and approved by IEC of SIU (CT).

3. Responsibility

The Chairperson, Member Secretary and all members as well as experts invited to advise the IEC of SIU (CT) should conduct a risk benefit analysis before approving the research.

4. Detailed Instructions

All actions are associated with some amount of risk that needs to be taken, so that a benefit could be achieved. Most prudent human beings carefully analyse the risk benefit ratio before undertaking any action. This principle holds good, in research too.

Risk may be to the individual participant, the society or the community as a whole. Additionally, there could be risk to the investigator, the research staff and to the other people who come into contact with the participants. The risk of the experiments to the environment, plant and animal life should also not be ignored. So also, a research project may give benefits to each of the above stakeholders. A careful analysis of the risk and benefits is required before approving or undertaking the research, ensuring that expected benefits always exceed expected risks.

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4.1 Categories of Risk

The ICMR classifies research projects in four groups with reference to the risk involved, as follows:

Type of risk	Definition/description
Less than minimal risk	Probability of harm or discomfort anticipated in the research is nil or not expected. For example, research on anonymous or non-identified data/samples, data available in the public domain, meta-analysis, etc.
Minimal risk	Probability of harm or discomfort anticipated in the research is not greater than that ordinarily encountered in routine daily life activities of an average healthy individual or general population or during the performance of routine tests where occurrence of serious harm or an adverse event (AE) is unlikely. Examples include research involving routine questioning or history taking, observing, physical examination, chest X-ray, obtaining body fluids without invasive intervention, such as hair, saliva or urine samples, etc.
Minor increase over minimal risk or Low risk	Increment in probability of harm or discomfort is only a little more than the minimal risk threshold. This may present in situations such as routine research on children and adolescents; research on persons incapable of giving consent; delaying or withholding a proven intervention or standard of care in a control or placebo group during randomized trials; use of minimally invasive procedures that might cause no more than brief pain or tenderness, small bruises or scars, or very slight, temporary distress, such as drawing a small sample of blood for testing; trying a new diagnostic technique in pregnant and breastfeeding women, etc. Such research should have a social value. Use of personal identifiable data in research also imposes indirect risks. Social risks, psychological harm and discomfort may also fall in this category.

More than minimal risk or High risk	Probability of harm or discomfort anticipated in the research is invasive and greater than minimal risk. Examples include research involving any interventional study using a drug, device or invasive procedure such as lumbar puncture, lung or liver biopsy, endoscopic procedure, intravenous sedation for diagnostic procedures, etc.

The IEC of SIU (CT) is required to make a risk benefit analysis. Unfortunately, there is no clear-cut classification of benefit, as it is for risks, but members of IEC of SIU (CT) need to make their own assessment about the expected benefit of the research. It is acknowledged that every research has some inherent risks and probabilities of harm or inconvenience to participants/communities. This involves a three-step process defined below:

4.1.1 Risk identification

Risks that are unidentified often get missed, if the researcher knows the risk to the participant by the study procedures, it becomes easy to identify and record them.

4.1.2 Risk quantification

The incidence and severity of the risk should be evaluated, hence quantification of the risk helps better assessment of risk benefit analysis.

4.1.3 Risk management

Risk management has a number of aspects, excluding people who are at risk is the first and foremost, additionally reduction of risk or maximization of benefits helps tilt the balance in favour of benefits.

A general ethical principle of ICMR is that the researcher, sponsor and EC should attempt to maximize benefits and minimize risks, so that the research leads to more benefits at individual, societal and/or community levels.

4.2 Categories of Benefit

Any experiment or research could lead to the benefit to the individual participant, other patients, or the society or community at large. In a way, research benefits the investigator, sponsor and the site too. However monetary benefits to these entities should not be the driver for research.

It is also not easy to quantify benefits, but they could include the following but are not restricted to:

4.2.1 Reduction of morbidity and mortality

4.2.2 Improvement in the quality of life

4.2.3 Reduction of the financial burden on the patient or community

4.2.4 Increase in convenience for the patient, family or society

4.3 Risk Benefit analysis

Neither risks nor benefits are easily quantifiable, hence the need for their balance at the hands of experienced IEC of SIU (CT). The members of the IEC of SIU (CT) must use their collective wisdom to decide whether the benefits outweigh the risks before approving any proposal.

5. Risks and potential benefits

The justification of predictable risks and inconveniences are weighed against the anticipated benefits for the research participants and the concerned communities. It is admitted that there could be unforeseen risks, but they would come to light only when the study begins. If risks, unforeseen at the time of approval, appear during the course of the study, members of the IEC of SIU (CT) must take a call on the continuation of the study.

Members of the IEC of SIU (CT) should also assess the justification for the use of control arms; placebos, comparative treatments while approving the research study. It may sometimes turn out that the study poses extra risk to some participant(s) but not others, members of IEC of SIU (CT) should consider whether to withdraw the participant(s) at risk while allowing the study to continue.

Plans to withdraw or withhold standard therapies for demonstrating the efficacy or safety of trial drugs or procedures and justification for such action, should be carefully considered before approval. Members of IEC of SIU (CT) should review the criteria for suspending or terminating the research if the balance shifts towards risk at any stage of the study.

6. References

6.1 New Drugs and Clinical Trial Rules 2019

6.2 National Ethical Guidelines for Biomedical and Health Research Involving Human Participants. 2017.

Function	Name	Designation	Signature
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Approved by	**Dr. Raman Gangakhedkar**	**Chairman**	

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Informed Consent

1. Purpose

The purpose of this SOP is to describe the information and essential elements required to be included in the informed consent documents associated with research study.

To describe the procedure for obtaining voluntary informed consent from a prospective subject for a research study and also to ensure that a subject's consent is sought in such a way that the subject or his/her representative has ample opportunity to consider whether to participate in the study and under conditions that minimize the possibility of coercion or undue influence.

To ensure that freely and voluntarily given written Informed Consent is obtained from each participant in accordance with applicable regulatory requirement, Schedule Y, NDCTR 2019, ICH-GCP and Declaration of Helsinki.

2. Scope

All studies conducted in SIU, or those reviewed and approved by IEC of SIU (CT) shall be conducted only after obtaining a written informed consent from participants. The Informed consent could be a single document, or two different documents, a Patient Information Sheet and the Consent document. Informed consent document (ICD) is also known as Informed Consent Form.

3. Responsibility

The Chairperson and Member Secretary along with other members of IEC of SIU (CT) are responsible to ensure that the Informed Consent Documents are complete, and contain all the essential elements as required by the NDCTR and ICMR. All members must ensure that the technical terms in the ICD are explained in a simple manner. The lay person should ensure that the language of the document is such that another lay person can comprehend it. The legal member must ensure that the ICD contains no phrase that waives rights of the participants. Members should examine the translations of the ICD (to the extent possible to ensure that the translations are accurate).

4. Detailed Instructions

Informed Consent is not merely a document, it is a process which is ongoing throughout the study. The participant has a right to take time to study the document, ask any questions she/he may have, show the document to family and friends for consultation, before signing the same.

4.1 Contents of the ICD

The ICD must contain the following elements:

4.1.1 Statement that the study involves research and explanation of the purpose of the research.

4.1.2 Expected duration of the participation of subject.

4.1.3 Description of the procedures to be followed, including all invasive procedures.

4.1.4 Description of any reasonably foreseeable risks or discomforts to the Subject.

4.1.5 Description of any benefits to the Subject or others reasonably expected from research. If no benefit is expected Subject should be made aware of this.

4.1.6 Disclosure of specific appropriate alternative procedures or therapies available to the Subject.

4.1.7 Statement describing the extent to which confidentiality of records identifying the Subject will be maintained and who will have access to Subject's medical records.

4.1.8 Trial treatment schedule and the probability for random assignment to each treatment (for randomized trials).

4.1.9 Statement describing the financial compensation and the medical management as under:

4.1.9.1 In case of an injury occurring to the subject during the clinical trial, free medical management shall be given as long as required or till such time it is established that the injury is not related to the clinical trial, whichever is earlier.

4.1.9.2 In the event of a trial related injury or death, the sponsor or his representative or the investigator or centre, as the case may be, in accordance with the rule 39, as the case may be, shall provide financial compensation for the injury or death.

4.1.10 An explanation about whom to contact for trial related queries, rights of Subjects and in the event of any injury.

4.1.11 The anticipated prorated payment, if any, to the subject for participating in the trial.

4.1.12 Responsibilities of subject on participation in the trial.

4.1.13 Statement that participation is voluntary, that the subject can withdraw from the study at any time and that refusal to participate will not involve any penalty or loss of benefits to which the subject is otherwise entitled.

4.1.14 Statement that there is a possibility of failure of investigational product to provide intended therapeutic effect. (xv) Statement that in the case of placebo controlled trial, the placebo administered to the subjects shall not have any therapeutic effect.

4.1.15 Any other pertinent information

The following additional elements may be required for some studies:

a) Statement of foreseeable circumstances under which the participation of the subject may be terminated by the Investigator without his or her consent.

b) Additional costs to the subject that may result from participation in the study.

c) The consequences of a Subject's decision to withdraw from the research and procedures for orderly termination of participation by Subject.

d) Statement that the Subject or Subject's representative will be notified in a timely manner if significant new findings develop during the course of the research which may affect the Subject's willingness to continue participation will be provided.

e) A statement that the particular treatment or procedure may involve risks to the Subject (or to the embryo or foetus, if the Subject is or may become pregnant), which are currently unforeseeable.

f) Approximate number of Subjects enrolled in the study.

4.2 Format of the ICD

The following is required in the ICD

4.2.1 Informed Consent form to participate in a clinical trial
4.2.2 Study Title
4.2.3 Study Number
4.2.4 Subject's Initials
4.2.5 Subject's Name
4.2.6 Date of Birth/Age
4.2.7 Address of the Subject
4.2.8 Qualification
4.2.9 Occupation
4.2.10 Annual Income of the subject

4.2.11 Name and address of the nominees and his relation to the subject (for the purpose of compensation in case of trial related death).

4.2.12 The form must have a signature of the subject and thumb impression and signature of the impartial witness, LAR when applicable

The following is required in the ICD

a) I confirm that I have read and understood the information [ ] Sheet dated _____ for the above study and have had the opportunity to ask questions.

b) I understand that my participation in the study is voluntary and [ ] that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.

c) I understand that the Sponsor of the clinical trial, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published. [ ]

d) I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purposes [ ]

e) I agree to take part in the above study. [ ]

f) Signature (or Thumb impression) of the Subject/Legally Acceptable Representative:

Date: _____/ ____ /

Signatory's Name: _____

Signature of the Investigator: _____ Date: ____ / ____ /

Study Investigator's Name: ___ _____

Signature of the Witness _____ Date: ____ / ____ / Name of the Witness:_____

Copy of the Patient Information Sheet and duly filled Informed Consent Form shall be handed over to the subject his or her attendant

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5. Informed Consent Process:

Informed consent is appropriately documented, in accordance with, and to the extent required by NDCTR, ICMR Guidelines, EC and Institutional regulations.

The ICD should be administered in a quiet place where the potential participant and the investigator can have a quiet talk. The place should be free from other people and other disturbances.

EC evaluates that following measures were taken by Investigators while obtaining consent:

5.1 Consent interview conducted by delegated study person.

5.2 The person who will provide consent or permission.

5.3 Any waiting period between informing the prospective participant and obtaining consent.

5.4 The language used by those obtaining consent.

5.5 The language understood by the prospective participant

5.6 Steps taken to minimize the possibility of coercion or undue influence.

5.7 Study design & study treatments

5.8 Details discussion about Risks & benefits involved

5.9 Information provided about Compensation & medical reimbursement

5.10 Protection of Privacy & confidentiality

5.11 Rights & Responsibilities of subject

5.12 Alternative available treatment options

5.13 Investigator & EC details

5.14 Satisfactory answers to queries asked by subject/LAR

5.15 Voluntary participation & withdrawal

6. Audio-visual Recording

As per the Drugs Controller General of India regulations informed consent process should be recorded using an audio-visual recorder. Accordingly, the investigator should record the informed consent process for each subject. AV recording is mandatory when the clinical trial involves a new drug and vulnerable participants. In other cases, AV recording is optional if the investigator and participants both agree. However, in case of studies on HIV and Leprosy no video recording is permitted, only audio recording be made and stored.

The following actions will be taken in this regard:

6.1 Facilities for recording consents, available in the hospital only will be used for recording.

6.2 After recording the CD/DVD or any other storage medium will be password protected and stored by the investigator.

6.3 The recordings will not be displayed before any individual other than those mentioned below:

6.3.1 Members of the Ethics Committee, on a written request approved by the Chairperson IEC.

6.3.2 Regulatory Representative, who have been duly identified.

6.3.3 Representatives of Courts who have the jurisdiction, on the orders of the court.

6.4 The recordings shall be stored with all other trial documents and destroyed only when other documents are destroyed on the instructions of the sponsor.

7. Waiver/Alteration

7.1 EC does not allow any type of waiver / alteration in ICD/process, except those allowed by regulations in certain situations. No other waiver of Informed consent or the documentation of informed consent process shall be granted.

7.2 EC considers the following for waiver of the documentation of informed consent process.

7.2.1 The research involves no more than minimal risk to the subjects;

7.2.2 The waiver or alteration will not adversely affect the rights and welfare of the subjects;

7.2.3 Whenever appropriate, the subjects will be provided with additional pertinent information after participation. The Investigator will provide subjects with a written statement regarding the research.

7.2.4 Any other conditions as per the discretion of EC Chairperson

7.3 EC may consider the waiver for Informed consent of subject and/ subject's legal representative in case of Emergency use of Investigational product, provided that following is documented by the Investigator before the use of Investigational product

7.3.1 The subject is confronted by a life-threatening situation necessitating the use of the Investigational product

7.3.2 Informed consent cannot be obtained from the subject because of an inability to communicate with, or obtain legally effective consent from the subject.

7.3.3 Time is not sufficient to obtain consent from the subject's legal representative.

7.3.4 There is no available alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the subject.

7.3.5 It is recommended that, as soon as the subject recovers, or is capable of consenting, consent is obtained from the subject or the subject's legal representative.

8. Additional Information

8.1 **Advertisement materials:** EC reviews the information contained in the advertisement, the mode of its communication, the final copy of printed advertisements, the final audio or video taped advertisements. EC will confirm whether this is limited to the information, which the prospective subject may need to determine their eligibility and interest. This will include following:

8.1.1 The name and address of the Investigator or research facility

8.1.2 Purpose of the research or the condition under study

8.1.3 A brief summary form, which specifies the eligibility for the study.

8.1.4 A brief list of benefits to the subjects if any.

8.1.5 'Time and any other commitment required from the subject.

8.1.6 Detail contact information that is location of the research and the delegated person's number/office number etc.

8.2 EC also reviews the advertising material to ensure that advertisements do not

8.2.1 State or imply a certainty of favourable outcome or other benefits beyond what is outlined in the consent document and the protocol.

8.2.2 Make claims, either explicitly or implicitly about the drug, biologic or device under investigation that are inconsistent with approved labelling.

8.2.3 Used terms such as "new treatment", "new medication" or "new drug" without explaining that the test article is investigational.

8.2.4 Allow compensation for participation in a trial offered by a sponsor to include a coupon good for a discount on the purchase price of the product once it has been approved for marketing.

8.2.5 Include exculpatory language.

8.2.6 Emphasize the payment or the amount to be paid, by such means as larger or bold type.

8.2.7 Promise "free treatment" when the intent is only to say participants will not be charged for taking part in the investigation.

9. **References**

9.1 New Drugs and Clinical Trial Rules 2019

9.2 National Ethical Guidelines for Biomedical and Health Research Involving Human Participants. 2017

Function	Name	Designation	Signature
Prepared by	**Dr. Manjiri Joshi**	**Head, Clinical Research Dept, SUHRC & SMCW**	
Reviewed by	**Dr. Ravindra Ghooi** **Dr T. Vijaya Sagar**	**Member, IEC** **Dean, SMCW**	
Approved by	**Dr. Raman Gangakhedkar**	**Chairman**	

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Waiver of informed consent

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe the type of research projects for which the IEC of SIU (BHR) may grant waiver of the requirement of obtaining written informed consent and provides the format of the application form to be used by the investigators for requesting waiver of consent.

2. Scope

This SOP applies to all protocols submitted for review to the IEC of SIU (BHR) with a request of granting waiver of consent. The decision of waiver should be taken by the members of IEC of SIU (BHR) during a full board meeting.

3. Responsibility

It is the responsibility of the IEC of SIU (BHR) to review and approve a request for waiver of written consent. The Member Secretary will record the decision in the application form. The Member Secretary / Chairperson must sign and date the letter conveying the decision to the PI.

4. Detailed instructions

When a request for waiver of consent is submitted by the principal investigator along with the study documents to the IEC of SIU (BHR) Secretariat, the following steps will be taken:

4.1 The Secretariat of IEC of SIU (BHR) will check if the concerned documents are filled completely and the required list of documents is enclosed.

4.2 Members of the IEC of SIU (BHR) will review the request taking into consideration the type of study to grant waiver of consent.

4.3 The IEC of SIU (BHR) will ensure that there are adequate mechanisms described in the protocol for protection of the identity of the research participants and maintaining

confidentiality of the study data. (This is necessary as the participant cannot be assured directly about confidentiality of health data through a formal informed consent process, when waiver of consent is granted.)

4.4 The decision whether to grant the waiver will be taken during full board meeting.

4.5 The decision regarding approval/disapproval of waiver of consent will be informed to the principal investigator in writing within 10 days of the IEC of SIU (BHR) meeting. If the waiver is not granted, the IEC of SIU (BHR) will provide reasons for the same.

5. Type of research projects which may qualify for waiver of consent:

A request to waive written informed consent must be accompanied by a detailed explanation. The investigator is also required to provide assurance regarding protection of identity of research participants and maintenance of confidentiality about the data of the research participants. The following criteria, as per ICMR 2017 guidelines must be met for a research project so that it can qualify for granting a waiver of written consent.

5.1 The proposed research presents no more than minimal risk to subjects. e.g. a retrospective review of patient case records to determine the incidence of disease/ recurrence of disease. [Minimal risk would be defined as that which may be anticipated as harm or discomfort not greater than that encountered in routine daily life activities of general population or during the performance of routine physical or psychological examinations or tests. However, in some cases like surgery, chemotherapy or radiation therapy, greater risk would be inherent in the treatment itself, but this may be within the range of minimal risk for the research participant undergoing these interventions since it would be undertaken as part of current everyday life].

5.2 When it is impractical to conduct research since confidentiality of identifiable information has to be maintained throughout research as maybe required by the sensitivity of the research objective. E.g.: *conducting interviews with citizens about their religious beliefs/ people with HIV and AIDS/conducting phone interviews with homosexuals.* The only record linking the participant and the research would be the consent document and when there is a possible legal, social or economic risk to the participant entailed in signing the consent form as they might be identified as such by signing the consent form, the requirement for obtaining consent can be waived by the IEC of SIU (BHR). [In case of telephonic interviews, waiver of written informed consent may be requested but verbal consent is mandatory].

5.3 Research on publicly available information, documents, records, work performances, reviews, quality assurance studies, archival materials or third-party interviews, service programs for benefit of public having a bearing on public health programs, and consumer acceptance studies.

5.4 Research on anonymized biological samples from deceased individuals, left over samples after clinical investigation, cell lines or cell free derivatives like viral isolates, DNA or RNA from recognized institutions or qualified investigators, samples or data from repositories or registries, etc.

5.5 In emergency situations when no surrogate consents can be taken when consent of person/ patient/ responsible relative or custodian/ team of designated doctors for such an event is not possible, the IEC of SIU (BHR) can allow waiver of consent for recruiting participant in a research study. However, afterwards information about the intervention should be given to the patients whenever he/she regains consciousness or to relative/ legal guardian.

6. References:

6.1 National Ethical Guidelines for Biomedical Research on Human Participants, ICMR (2017)

6.2 National Guidelines for Ethics Committees Reviewing Biomedical & Health Research During Covid-19 Pandemic, ICMR 2020.

Function	Name	Designation	Signature
Prepared by	**Dr. Manjiri Joshi**	**Head, Clinical Research Dept, SUHRC & SMCW**	
Reviewed by	**Dr. Ravindra Ghooi** **Dr T. Vijaya Sagar**	**Member, IEC** **Dean, SMCW**	
Approved by	**Dr. Raman Gangakhedkar**	**Chairman**	

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Meeting procedures and recording minutes

1. Purpose

The purpose of this SOP is to describe administrative processes and provide instructions for preparation, review, approval, and distribution of meeting agenda, minutes, and notification letters of IEC of SIU (CT) meetings

Maximum interval between 2 regular meetings will be less than three months and this frequency will be modified from time to time depending on the research proposals received for review

Venue: Meeting hall in MS office ground floor, when meeting is in person,

Or

Any other venue as specified in the agenda notice

Or

Virtual meeting as per the link provided

2. Scope

This SOP applies to administrative processes concerning the conduct of the meeting

3. Responsibility

It is the responsibility of the Member Secretary, and IEC of SIU (CT) staff to make preparations for the IEC of SIU (CT) meeting, by preparing the agenda, and organizing venue and fixing a time. The Member Secretary with the help of the Secretariat will ensure timely distribution of the documents of the studies to be discussed. They would ensure that all members of the IEC of SIU (CT) receive the entire agenda and documents in time and ensure that all members attend the meeting.

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The Chairperson will ensure that the quorum is complete and that every member declares his/her conflict of interest (CoI) if any. The members of IEC of SIU (CT) are responsible to read and approve the minutes of the previous meeting sent to them, and keep their suggestions ready for discussion. The Chairperson will review and approve the minutes, if no member has any comments to make on the minutes at the beginning of the SIU (CT) meeting.

It is the responsibility of the Member Secretary to ensure proper recording of the discussion using an audio recorder or recording the virtual meeting as the case may be to ensure accuracy of the minutes that are prepared.

4. Detailed instructions

The IEC of SIU (CT) full board meeting will be scheduled at least once in 3 months, the meeting may be organized more often in case there is a higher number of proposals for review. During the meeting of the IEC of SIU (CT) the following business will be transacted.

4.1 Regular matters

4.1.1 Leave of absence to members who have conveyed their inability to attend.

4.1.2 Ensuring quorum fulfilment by the Chairperson

4.1.3 Reading and approving minutes of the previous meeting

4.1.4 Review of protocols and related documents on agenda.

4.1.5 Review of amendments/ deviations / notifications

4.1.6 Review of site SAE reports / CIOMS forms / minutes of SAE subcommittee

4.1.7 In every meeting, a tentative date of the next meeting will be decided.

4.2 Additional matters (to include as applicable)

4.2.1 Continuing review of ongoing studies

4.2.2 Review of study completion reports

4.2.3 Review of premature study termination

4.2.4 Review of site monitoring visits

4.2.5 Discussion on emergency concerns / IEC of SIU (CT) policies / training of members / revising SOPs / any other issues raised by the members

4.3 Any other matter with the permission of the chair.

4.3.1 Study-related document (except those related to the safety of a participant including SAE report) received less than 10 days preceding the date of meeting will not be considered for the meeting. The Member Secretary or Chairperson may however accept any document of discussion if they feel it requires urgent attention.

4.3.2 Replies of the PI queries of members of IEC of SIU (CT) and amended study related documents (protocol, ICD, CRF, IB, etc.) received 5 days prior to the date of the IEC of SIU (CT) meeting will be included in the agenda.

4.3.3 Protocols will be scheduled on the agenda on a first come first serve basis and completeness of the document submitted or availability of PI to attend the meeting.

4.3.4 In case a meeting is rescheduled due to unavoidable circumstances, the same will be informed to the members and the date and time will be informed to the IEC of SIU (CT) members telephonically and/or via e-mail.

4.3.5 The Secretariat will remind the IEC of SIU (CT) members of the meeting telephonically and check the confirmation of attendance one day prior to the meeting.

4.4 Distribution of protocol / document packages to the IEC of SIU (CT) Members

4.4.1 Copies of the protocols and/or other documents will be distributed / delivered to the members of IEC of SIU (CT) via e-mail (in case of electronic submission of protocols). The receipt of the documents to members will be verified either telephonically or by e-mail.

5. Meeting procedures

5.1 Meeting will be held as scheduled provided the Chairperson ensures that the quorum requirement is met.

5.2 At the discretion of the Chairperson, guests such as students, inspectors, auditors, experts, members of other ethics committees, surveyors, regulators, members of regulatory agencies, representatives of patient groups/ special interest groups, representatives of accrediting organizations, members of general public, etc. may be allowed to observe the board meeting. These observers may not comment or vote for any proposal under discussion.

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5.3 The Secretariat will obtain signatures on the confidentiality agreement from such observers who are not members of IEC of SIU (CT).

5.4 The Secretariat will obtain the signatures of all IEC of SIU (CT) members on the attendance register.

5.5 The Chairperson at his/ her discretion may delegate the responsibility of conducting the meeting as per agenda to any other member.

5.6 The Chairperson will ensure declaration of conflict of interest by any member of the committee in any project at the start of the meeting.

5.7 The Secretariat will obtain signatures on the conflict of interest agreement form from members who declare a conflict (e.g.: members who are PI or Co-PI or have an association with the PI/Co-PI/CRO /sponsor) prior to the start of the meeting.

5.8 If any member of IEC of SIU (CT) has a conflict of interest in a project then the Chairperson may ask him / her to leave the room when the concerned project is being discussed. He/ she will not participate in discussion and decision process. This will be recorded in the minutes. However, the member may provide answers to queries of the committee members.

5.9 The meeting will proceed in the sequential order of the agenda; however, the Chairperson may allow adjustments in the order of issues to be discussed, if the situation so demands.

5.10 The IEC of SIU (CT) will invite investigators to attend the full board meeting related to their studies, and clarify points raised by the committee members. The PI / Co-PI will present the study in brief. The primary reviewers will offer their comments (if he/she is unable to attend, their comments sent on e mail will be read out by the Member Secretary), followed by discussion between the members of IEC of SIU (CT). The discussion amongst members of IEC of SIU (CT) and the decision will not be taken while the PI is in the meeting room.

5.11 For other points on the agenda, the Member Secretary will present the summary of the matter/ read the relevant letters (if deemed necessary) and request the members to offer comments.

5.12 The Member Secretary & members of Secretariat will take notes of the proceedings of IEC of SIU (CT) meeting.

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6. Decision making process

6.1 The committee will review new project proposals, amendments, annual progress of ongoing projects, SAE reports, and assess final reports of all research activities through a scheduled agenda

6.2 Members of IEC of SIU (CT) who have a CoI will withdraw from the meeting or desist from offering any opinion during the decision making process concerning an proposal where a CoI exists

6.3 No new study will be discussed in the absence of the PI or Co-PI.

6.4 Decisions will only be taken at meetings where a quorum (SOP02/V6) is present.

6.5 Opinion of only those members of IEC of SIU (CT) who attend the meeting will be valid.

6.6 Decisions will be arrived at through a consensus. When a consensus is not possible, the members of IEC of SIU (CT) will vote. A majority vote is defined as 50% of members in attendance plus one. In case of an equal vote on both sides, the Chairperson will get an additional vote (casting vote).

6.7 Decisions will include approval, disapproval, request for modifications of a study, suspension or termination of studies, and other items discussed.

6.8 If the full board approves a research proposal in principle subject to minor modifications, the revised project proposal submitted by the PI will be reviewed and approved by the Member Secretary IEC of SIU (CT) or by members on behalf of the full board designated by the Chairperson to do so. Such revised proposals will not be taken up for the full board review. However, in case of major changes, the revised documents will be discussed in the full board meeting, this decision will be taken by the Chairperson.

6.9 Even if the quorum is not complete, the studies can be discussed during the IEC of SIU (CT) meeting. However, decision of approval / disapproval will be taken at the next scheduled meeting in presence of the desired quorum.

IEC of SIU (CT) may decide to reverse its positive decision on a study if it receives information that may adversely affect the risk/ benefit ratio. Similarly, it may approve or disapprove a study on receipt of additional information or clarifications.

6.10 In case of conditional decisions, clear suggestions for revision and the procedure for having the application reviewed again will be specified.

6.11 A negative decision on an application will be backed by clearly stated reasons. If the investigator wishes to appeal for revision of decision, he/she may do so by contacting the IEC of SIU (CT) Secretariat.

The discontinuation of a trial will be recommended if the IEC of SIU (CT) finds that the goals of the trial have already been achieved midway or unequivocal results are obtained.

6.12 The final decision on the study will be recorded in the decision form (annexure1) and signed and dated by all members and confirmed by the Chairperson during the meeting.

6.13 The schedule of the next meeting will be discussed and finalized by the members.

7. Post meeting activities

7.1 The Member Secretary will compile the proceedings of IEC of SIU (CT) meeting in a concise and easy-to-read style, and check spelling, grammar and context of the written minutes. The minutes of the meeting will be compiled within 5 working days of the meeting. The Secretariat will ensure that all the contents in each specific category as per the agenda will include the following –

7.1.1 Location where the meeting was held

7.1.2 Meeting number, date / time of commencement of the meeting

7.1.3 Name of IEC of SIU (CT) members and guests attending the meeting

7.1.4 Name of the Chairperson of the meeting

7.1.5 Confirmation of quorum by the Chairperson to proceed with the meeting.

7.2 Requirements for minuting of each study or activity discussed:

7.2.1 Sponsor's name

7.2.2 Protocol number/ date/ version of protocol when available

7.2.3 PI and/or Co-PI name

7.2.4 Name of the lead discussant(s) who presented his / their assessment/s

7.2.5 Discussion as deemed appropriate by the Chairperson

7.2.6 Follow-up action decided upon

7.2.7 Determination of the next continuing review

7.3 Requirements for each study or activity requesting expedited review

7.3.1 Sponsor's name

7.3.2 Protocol number

7.3.3 PI and/or Co-PI name

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7.4 Requirements for each continuing review report

7.4.1 Sponsor's name

7.4.2 Protocol number

7.4.3 PI and/or Co-PI names

7.4.4 Indication of the committee's decision to continue, terminate, or amend the study

7.4.5 List of recommendations or actions to be taken up with the PI, if applicable

7.5 Requirements of each SAE notification and final report

7.5.1 Sponsor's name, if applicable

7.5.2 Protocol number, if applicable

7.5.3 PI and/or Co-PI names

7.5.4 Report or summary of report if provided by the SAE sub-committee (if applicable)

7.5.5 Actions deemed appropriate by the committee

7.6 Requirements for termination of approval

7.6.1 Sponsor's name, if applicable

7.6.2 Protocol number, if applicable

7.6.3 PI and/or Co-PI names; reason(s) for termination

7.7 Approval of the minutes and the decisions

7.7.1 The Secretariat will check the correctness and completeness of the minutes and will email the minutes to the IEC of SIU (CT) members within 10 working days.

7.7.2 The minutes of the IEC of SIU (CT) meeting will be ratified in the subsequent meeting. The minutes of the IEC of SIU (CT) meeting will be signed by the chairman (after approval) and the decisions will be communicated to the PIs after the IEC of SIU (CT) meeting.

7.8 Filing the minutes

The Secretariat will file the original version of the minutes in the minute's file and the decision forms in the project files and place all correspondence in the appropriate files.

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7.9 Calling an unscheduled meeting of IEC of SIU (CT)

The Member Secretary in consultation with the Chairperson may decide to call an emergency meeting for any one or more of the following reasons:

7.9.1 Urgent issues (which if not decided upon early could have adverse impact on patient safety, public safety or national economy, etc.)

7.9.2 Occurrence of serious adverse event(s)

7.9.3 Other reasons as deemed appropriate by the Member Secretary / Chairperson

7.9.4 The Secretariat will contact every member and inform about the date, time and venue of the meeting as well as the reason for calling the meeting. The information and/ or reminders may be sent using other electronic media.

7.9.5 The Secretariat will prepare packets for distribution to the members containing the information and documents about the matter(s) for which the emergency meeting is scheduled or send the relevant details via email.

7.9.6 There shall be no procedural difference between a regular scheduled meeting and an emergency meeting.

7.10 Communicating decisions

7.10.1 The decision taken in the meeting of IEC of SIU (CT) will be communicated in writing to the PI, preferably within a period of 15 days of the meeting at which the decision was made.

7.10.2 The communication of the decision will be as per the annexure 2 for this purpose.

8. References

1.	International Council on Harmonisation, Guidance on Good Clinical Practice (ICH GCP) 1996 Retrieved from- *http://www.ich.org/LOB/media/MEDIA482.pdf*
2.	World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, (Geneva 2000)- Retrieved from- *www.who.int/tdr/publications/publications/*
3.	New Drugs and Clinical Trials Rules, 2019 [GSR 227(E) – 19 Mar 2019]

Glossary

Agenda: A list of things to be done; a program of business for the meeting

Minutes: An official record of proceedings at a meeting.

Quorum: Number of IEC of SIU (CT) members required to act on any proposal presented to the committee for action.

Function	Name	Designation	Signature
Prepared by	**Dr. Manjiri Joshi**	**Head, Clinical Research Dept, SUHRC & SMCW**	
Reviewed by	**Dr. Ravindra Ghooi** **Dr T. Vijaya Sagar**	**Member, IEC** **Dean, SMCW**	
Approved by	**Dr.Raman Gangakhedkar**	**Chairman**	

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IEC for Clinical Trials, Bioavailability (BA) and Bioequivalence (BE) Studies	Title: Reporting of SAEs	SOP No: D2: Reporting of SAEs
	Version: 02	Preparation Date: 18 June 2021
	Effective Date:	Review Date:

Reporting of Serious Adverse Events

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe procedures for the review of initial and follow up reports of serious adverse events (SAE) and unanticipated problems reported at site for all ongoing studies.

2. Scope

This SOP applies to the review of adverse events/serious adverse events and unanticipated problems reported on site as well as off site in clinical studies/trials approved by the IEC of SIU (CT).

3. Responsibility

The responsibilities for different parts of this activity are divided as follows:

Sr.No	Activity	Responsibility
1.	Reporting of SAEs/unanticipated events to IEC of SIU (CT) as per regulatory timelines	Investigator and research staff
2.	Receipt of SAE report	IEC of SIU (CT) Secretariat
3.	Include SAE report in agenda for discussion in IEC of SIU (CT) meeting	IEC of SIU (CT) Secretariat
4.	Review and discussion of all SAEs and unanticipated events reported to the IEC of SIU (CT)in a timely manner	Chairperson, Member Secretary and members of IEC of SIU (CT)
5.	Communication of decision of the IEC of SIU (CT) about SAE to the Licensing authority	Chairperson and/or Member Secretary
6.	Review of off site SAEs	Member Secretary or designee

4. Detailed Instructions

4.1 Definitions

4.1.1 **Serious Adverse Event**: Any untoward medical occurrence that at any dose results in death, is life threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect is termed an SAE. Additionally, the sponsor may identify some other incident as an SAE for a particular trial.

4.1.2 **Adverse Event:** An AE is any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and that does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product.

4.2 Investigators and members of the IEC of SIU (CT) must follow the procedure and timelines of reporting described in current regulations for serious adverse events.

4.3 The primary responsibility of the members IEC of SIU (CT) is to review and assess SAE and unexpected events causing risks to research participants and provide their opinion on the relatedness to trial products or procedures. Depending on the causality the members of IEC of SIU (CT) recommend to the DCGI the reimbursement of medical/surgical expenses incurred by the participant in treating the SAE, and compensation in case of permanent injury or death of the participant.

5. Onsite SAEs:

5.1 Reporting of onsite SAEs:

IEC of SIU (CT) should also make sure that Investigators are made aware of the policies and procedures concerning reporting SAEs.

5.1.1 Investigator should send SAE/death report within 24 hrs of the occurrence of event to Central Licensing authority (DCGI), Chairperson of the Ethics Committee, Sponsor and head of the institute in the recommended format of New Drug and Clinical trial Rule, 2019. (See Table 5 of Third Schedule NDCTR)

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5.1.2 Investigator should send detailed analysed report in prescribed format within 14 days of its occurrence as per Table 5 of the Third schedule and in compliance with the procedures specified in Chapter VI if New Drug and Clinical rule, 2019 to the Central Licensing authority (DCGI), Chairperson of the Ethics Committee, Sponsor and Head of the Institute. The information may include a summary of events in chronological order from date of admission till resolution / death, causality, subject's status etc

5.1.3 The reporting shall be done in Hard copy and/or via email.

5.1.4 All deaths, of participants in clinical trials whether related or not related, must be reported to the IEC of SIU (CT) and the same will be discussed in IEC of SIU (CT) meetings

5.1.5 The Secretariat of IEC of SIU (CT), on receipt of analysed report of SAE will send it to members of IEC of SIU (CT) in hard copy or via email.

5.1.6 The case shall be presented in full board meeting by study team.

5.1.7 The reported SAE shall be evaluated in the meeting of IEC of SIU (CT), keeping in view the opinion of the PI.

5.1.8 If IEC of SIU (CT) finds information about SAE inadequate, additional information may be requested, the Chairperson of IEC of SIU (CT) may invite an expert to advice the members if necessary.

5.1.9 The decision on causality be arrived at by consensus, however if consensus is not reached, a majority decision may be taken.

5.1.10 If appropriate, specific action might be taken, based on the decision of the EC. Some of which are listed below:

- Terminate the study;
- Withdraw the affected participant from the study.
- Put the study on hold.
- Suspend certain activities under the protocol (while going on with activities intended to protect the safety, well-being of participants who have already been enrolled);
- Recommend an amendment to the protocol, the ICD, participant information sheet, Investigator brochure and/ or any other document.
- Direct the Investigator to inform participants already enrolled in the study about the SAE and obtain their consent regarding continuation in the research trial, if necessary,

or request them to undertake additional visits, additional procedures, additional investigations, etc.

5.1.11 IEC of SIU (CT) shall communicate its decision to the Central Licensing Authority (DCGI) within 30 days of receiving the SAE report with a due analysis along with its opinion on reimbursement of medical treatment or compensation in accordance with the procedures specified in Chapter VI of New Drugs and Clinical Trial Rules, 2019) by email as well as hard copy.

5.1.12 Two original copies of Ethics Committee opinion shall be maintained. One copy shall be shared with the central Licensing Authority and one copy shall be retained for records.

5.2 Analysis of onsite SAE:

For analysis of causality of serious adverse events, Naranjo's algorithm should be used by IEC of SIU (CT). (See Annexure)

Naranjo's Scale:

- ≥ 9 = definite ADR
- 5-8 = probable ADR
- 1-4 = possible ADR
- 0 = doubtful ADR

Above assessment along with the compensation formula published by DCGI will be used to calculate compensation to be recommended to the trial subjects/nominees for trial related injury or death.

5.3 Offsite SAEs:

5.3.1 PI shall submit all SAEs on a monthly/quarterly/biannual basis in specified format.

5.3.2 The SAEs are checked and stamped by IEC of SIU (CT) secretariat and then forwarded to IEC of SIU (CT) Member Secretary or its designee (Preferably clinician of IEC of SIU (CT) for review.

5.3.3 If found adequate, the copy of letter shall be filed by IEC of SIU (CT) staff in respective study file.

5.3.4 If required, additional information may be requested for in depth review.

5.3.5 If any discrepancy noted, it conveyed to IEC of SIU (CT) meeting for discussion.

5.3.6 If required, appropriate action may be taken depending upon nature of discrepancy.

5.4 DCGI Query on Serious Adverse Events:

5.4.1 DCGI queries received by IEC of SIU (CT) shall answered by Member Secretary and/or Chairperson based on nature of the query.

5.4.2 In potentially contentious issues, as per Member Secretary and Chairperson's discretion, the correspondence may be brought to the notice of IEC of SIU (CT) members for discussion and decision.

5.4.3 The response or opinion shall be sent to DCGI within given timelines via email as well as via hard copy.

6. IEC of SIU (CT) Recommendation

6.1 It is the main duty of the IEC of SIU (CT) to protect the interests of the participants. Any participant who is injured due to his/her taking part in the trial deserves to be reimbursed the medical/surgical expenses made for the treatment of the injury, as long as deemed necessary. Additionally, the participant needs to be compensated in case of permanent injury or death.

6.2 The IEC of SIU (CT) must carefully evaluate the causality of each SAE and recommend to the Regulator the medical reimbursement and/or compensation that the sponsor should pay the participant. The reporting and recommendations of the IEC of SIU (CT) should be according to Rule 39, 40, 41 and 42 of the New Drugs and Clinical Trial Rules 2019.

6.3 The compensation in each deserving case must be calculated as per the formulae given in the aforementioned rules. At the end of the 90 days of the initial report of the SAE, the DCGI would provide the orders for payment of the compensation or otherwise. In case such orders do not come in time, the IEC of SIU (CT) should send a reminder to the DCGI, and ensure that the participant/nominee get the compensation as recommended.

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IEC for Clinical Trials, Bioavailability (BA) and Bioequivalence (BE) Studies	Title: Periodic Review and Oversight	SOP No: D3: Periodic Review and Oversight
	Version: 02	Preparation Date: 18 June 2021
	Effective Date:	Review Date:

Periodic review and Oversight

1. Purpose

The purpose of this SOP is to describe how periodic review of previously approved protocols should be managed by the IEC of SIU (CT).

The purpose of periodic review is to monitor the progress of the entire study which was previously approved; not just the changes in it, but to ensure continued protection of the rights and welfare of research subjects and the study conduct. Periodic review of the study may not be conducted through an expedited review procedure, unless

1.1 The study was eligible for, and initially reviewed by, an expedited review procedure; or

1.2 The study has changed such that the only activities remaining are eligible for expedited review.

2. Scope

This SOP applies to any periodic review of study protocols approved by IEC of SIU (CT) involving human subjects at pre-specified intervals not less than once a year. Depending upon the degree of risk to the participants, the nature of the studies and the vulnerability of the study participants and duration of the study, the IEC of SIU (CT) may choose to review the studies more frequently.

3. Responsibility

It is the responsibility of the Secretariat of IEC of SIU (CT) to remind the PIs and Member Secretary regarding periodic review of protocols at the correct interval. The IEC of SIU (CT) is responsible for reviewing the progress made in the protocol (number of patients recruited, dropped out, reasons for drop-out), the occurrence of unexpected events or problems, compliance of the PI regarding communications of the IEC of SIU (CT), and the rate of accrual of participants. All PIs will also apply for extension of approval of the project prior to the date of expiry of the approval. The IEC of SIU (CT) will review the status of all ongoing projects during every meeting in a predefined format.

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4. Detailed Instructions

All the approved protocols will be reviewed twice a year. It is the responsibility of the Member Secretary to ensure a decision regarding whether the project needs to be reviewed more frequently or not, as per the decision taken during the approval of the study. A fresh decision of additional review may be taken if required based on the SAE reports, monitoring reports, or safety concerns by the SAE subcommittee and Member Secretary.

4.1 Determine the date of periodic review

4.1.1 The Secretariat will look through the master sheet of projects approved by the IEC of SIU (CT) for the due dates of periodic reviews.

4.1.2 The Secretariat will plan for periodic review of annual progress reports to be reviewed at least two months ahead and as close as possible to the due date (i.e. at (no.) months after the date of original approval) of the protocol.

4.1.3 The Member Secretary / additional Member Secretary will include the annual project report/s in the agenda of the forthcoming IEC of SIU (CT) meeting for discussion for review.

4.2 Notify the principal investigator or the study team

4.2.1 The Secretariat will remind the PI at least one month before the due date for the periodic review in writing (via email or hard copy), requesting for a copy of the annual / periodic progress report to allow the study team sufficient time to collate the information and to prepare a report required for the periodic review.

4.2.2 The Secretariat will provide a periodic review application form (annexure) to the study team and file the acknowledgment in the master file of the research protocol.

4.2.3 Any PI who fails to submit the report for review within the stipulated time, will have to clarify the delay in writing, this will be forwarded to the Chairperson, IEC of SIU (CT).

4.2.4 In case of additional reviews, the Secretariat will remind the PI giving him/her sufficient time to prepare the report (at least (no.) weeks)

4.3 Manage periodic review package upon receipt

The Secretariat will receive duly signed and dated report submitted by the study team of periodic review for each approved protocol.

4.4 Verify the contents of the package

The Secretariat will ensure that the contents of the package include the following:

4.4.1 Periodic review application form (*annexure*)

4.4.2 Information about the number of participants enrolled to date and since the time of the last review, an explanation for any "yes" (ticked on the periodic review application form (*annexure*) answers on the application form and a discussion of scientific development, either through the conduct of this study or similar research that may alter risks to research participants. The changes in the selection criteria of participants, protocol / IEC of SIU (CT) consent document amendments, changes in the study team, any unexpected complications, etc. must have been discussed in the attached narrative.

4.4.3 The Secretariat will check for complete information and for the presence of the required signatures of the PI in the periodic review application form.

4.5 Filing the periodic review package

The administrative officer will file the periodic review package in master file of the research protocol.

4.6 Notify the members of the IEC of SIU (CT)

The Secretariat will distribute the protocol progress report to IEC of SIU (CT) members prior to the meeting.

4.7 Prepare meeting agenda

4.7.1 The Secretariat will follow for procedures on the preparation of meeting agenda and place the forwarded annual progress report on the agenda for the meeting of the IEC of SIU (CT), on the date which is as close as possible to the due date (i.e. at (no.) months or (no.) year after the date of original approval, whichever is earlier) of the protocol.

4.7.2 The Secretariat will additionally prepare the status report of all ongoing studies for the IEC of SIU (CT) to review and take appropriate action.

4.8 Protocol review process

The Chairperson / Member Secretary / members will use the periodic review application form (*annexure*) to guide the review and deliberation process. The IEC of SIU (CT) members could arrive at any one of the following decisions at the IEC of SIU (CT) meeting:

4.8.1 Noted and the project can be continued without any modifications

4.8.2 Modifications recommended – Protocols that have been suggested modifications by the IEC of SIU (CT) may not proceed until the queries raised by the IEC of SIU (CT) are resolved. Protocols should be amended and submitted to the IEC of SIU (CT) within (no.) months for re-review.

4.8.3 Disapproved / Discontinued: The reasons for discontinuation of the project should be mentioned in the letter notifying the decision to the PI.

4.9 The IEC of SIU (CT) Chairperson/ Member Secretary / additional Member Secretary will sign and date the IEC of SIU (CT) decision on the decision form (*annexure*) after a decision has been reached. This shall be recorded in the minutes of the meeting.

4.10 The IEC of SIU (CT) Secretariat will maintain and keep the IEC of SIU (CT) decision forms and minutes of the meeting relevant to the periodic review as part of the official record of the review process.

4.11 Store original documents

Place the original completed documents with the other documents in the periodic review package in the protocol file.

4.12 Communicate the IEC of SIU (CT) decision to the Principal Investigator

The Secretariat will notify the PI of the decision. If the decision is to recommend modifications, the recommendations will be notified to the Principal Investigator and he/she will be requested to resubmit the protocol/protocol related documents as amendment within one months for approval. Till then the project will be suspended. These letters must be sent to the principal investigator within (no.) days of the meeting that discussed the progress report.

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4.13 Non-submission of periodic review report by PI before due date:

If a PI fails to submit the periodic review report within one month of the due date, the Secretariat will send a written / telephonic and/or email reminder, and if the PI fails to respond the study approval will stand cancelled.

5. References

5.1 World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, (Geneva 2000)
www.who.int/tdr/publications/publications /

5.2 International Council on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 2016

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Approved by	**Dr.Raman Gangakhedkar**	**Chairman**	

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